

Roche Position on Product Stewardship¹

Roche's Position

Roche's business is to develop and offer high-quality medical and in-vitro diagnostic solutions for unmet medical needs. However, our products also have the potential to negatively impact people and the environment.

Roche has established an effective Safety, Security, Health and Environmental protection (SHE) management system, including internal guidelines, directives and auditing to continuously reduce the potential for negative impacts of our business operations. We adapt and apply principles from our SHE management system to address the potential for negative impacts from our products. Such efforts reflect Roche's commitment to Product Stewardship.

"Product Stewardship" (PS) 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 (e.g., manufacturers, retailers, users, and disposers) take responsibility for minimizing the negative impacts on people and the environment.² Specific to Roche, PS is the collection of actions taken to ensure that our medicines and diagnostic products are developed, produced, used and managed at end-of-life in a responsible manner.³

A key pillar of our PS program is to engage in open communication about SHE aspects of our products with our employees, shareholders and external stakeholders (e.g., physicians, nurses, pharmacists, laboratory workers, patients, lawmakers, governmental and non-governmental organizations, suppliers, waste handlers, and others as applicable).

In pursuing our PS initiatives Roche strives for SHE efficiency: i.e., using our available resources in a way that brings about the best overall result, through well-reasoned prioritization of SHE projects and activities.⁴

Our ultimate aim is to maintain a comprehensive and continuously improving PS Program that, from product inception through end-of-life, enhances the value of our products to society by minimizing negative impacts to people and the environment.

¹ Pertains to SDGs 3, 6, 7, 12 and 13.

² <https://www.epa.gov/sustainability/glossary-sustainable-manufacturing-terms>

³ http://www.roche.com/dam/jcr:5b95a6fa-f1a8-4c00-9219-86e5b8d70e82/en/cse-guidelines_assur_safety_env_protection.pdf

⁴ http://www.roche.com/dam/jcr:26cdac00-cbcd-462d-97c1-df87b2ceaa9b/en/she_policy.pdf

The global situation

Pharmaceuticals are biologically active molecules. If not handled properly, their adverse side effects can potentially affect medical professionals who prepare and/or administer them (nurses, pharmacists etc.). The prevention of effects in these target groups has increasingly become an objective of authorities responsible for occupational health.

In recent years, more and more countries have implemented policies and provisions to reduce pollution and the generation of wastes from products at end-of-life. In our industry, increased scrutiny is being paid to the presence of pharmaceuticals and other chemicals in water and food (i.e. Pharmaceuticals in the Environment, or “PIE”). The contribution to PIE from production processes and from disposal of unused medicines is generally accepted as small compared to the contribution from bodily excretion by patients).⁵ Nonetheless, there is growing political pressure on countries, and on companies, to reduce even the small contribution that comes from production and from disposal of unused medicines. There are also concerns about the possibility of injury and infection from improper disposal of “sharps” (e.g., used needles and lancets) and other medical devices and diagnostic equipment at end-of-life.

Faced with a significant increase of consumer waste, many countries have developed new strategies to address this issue. One strategy, Extended Producer Responsibility (EPR), includes placing the financial and/or physical responsibility for the post-consumer phase of certain goods on the producers.⁶ 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.

The regulatory environment for chemicals is growing more complex, especially impacting diagnostics by restricting the type and composition of materials that can be included in products and/or discharged as waste from diagnostic equipment, and requiring analysis and declaration of the materials contained in products, packaging and waste. Where there is a lack of harmonization of legislation between regions and countries it can significantly complicate compliance management.

The situation at Roche

Roche’s Product Stewardship program is designed to help reduce the SHE impact of our products. To achieve this aim we have developed internal directives, standards and guidelines which incorporate the following key policies and practices:

- **Responsibility:** Roche cares about people and the environment. We are a responsible

⁵ http://www.roche.com/dam/jcr:05ea28bc-d654-47cb-a6ae-9d46de15b29b/en/pharmaceuticals_in_the_environment.pdf

⁶ Refer to The Organization for Economic Co-operation and Development (OECD) ["Extended Producer Responsibility: A Guidance Manual for Governments"](#)

producer of medicines, diagnostic devices and kits, and we take seriously our responsibility to protect people and the environment from negative impacts of our products, throughout their entire life-cycle.

- **Goals to improve Product Stewardship:** We have established ambitious and challenging SHE goals in our operations (e.g., provisions on energy and water reduction, eco-balance, emissions, and waste reduction). As a result, Roche has been ranked as a global leader on sustainability indices for a number of years. We aim to improve further by more fully embedding product stewardship considerations within appropriate stages of product and packaging research and development processes. This enables us to address global regulatory requirements and product stewardship goals at product inception and throughout development processes. Additionally, Roche has set a specific corporate goal to phase out the use of Substances of Very High Concern (SVHCs).⁷
- **Development of “greener” products:** Our primary goal is to develop innovative medicines and diagnostic devices and kits to improve patients’ lives. However, from the point of conception of a new product we strive to optimize our processes and product design to minimize the use of resources (e.g., energy and water), including resources consumed by product distribution, and wastes generated by product use (e.g., packaging, consumable supplies and liquid wastes from diagnostic instruments). We also seek to reduce the use of hazardous substances and materials, and actively collaborate with other companies and organizations to develop and promote techniques for Green Chemistry and Green BioPharma manufacturing. As medicines are consumed, there is no possibility for re-use or recycling of these products. On the other hand, the switch from small molecule medicines to bio-molecules comes with a generally much better degradability of our products and thus a significantly reduced contribution to PIE.
- **Waste avoidance:** We strive to reduce the amount of packaging material required for shipping and storing our products and for re-using packaging material. As part of our commitment to personalized healthcare we develop medicines and “companion” diagnostics. The aim is to improve the first-time success rate for patient therapies by developing diagnostic tests to identify patients for whom our medicines are most likely to be effective. A potential added benefit of a higher success rate is that it may help reduce waste from medicines that are tried and then abandoned, mid-way through a course of therapy, due to lack of effectiveness.
- **“Take-back” programs:** Roche acknowledges the legitimate concerns of the global community for responsible management of unused pharmaceutical products, sharps and other medical devices at end-of-life, and we use safety data sheets and other

⁷ Refer to Environmental Goals;

http://www.roche.com/sustainability/what_we_do/for_communities_and_environment/environment/our_she_goals_and_performance.htm?acc2=tab6

means to inform healthcare providers and patients about how to responsibly manage our products.

Roche supports take-back programs in principle. If take-back programs are to be implemented they should contain elements that promote efficiency and effectiveness, including but not limited to:

- Shared responsibility for all relevant stakeholders
 - Maximal use of existing infrastructure
 - Oversight and evaluation to ensure programs efficiently meet stated objectives
 - Consumer education
- **Recycling:** Wherever technically feasible and practical we recycle chemicals (e.g. waste solvents from production processes, as well as parts of diagnostic devices). We also strive to design products and packaging that use recycled content, and can be re-used as a raw material or recycled at end-of-life.
 - **Waste disposal:** With respect to Roche operations, we strive to reduce waste and recycle what remains wherever feasible, and have established a clear policy that the landfilling of organic chemical and hazardous waste is to be avoided: such wastes must be incinerated whenever feasible.⁸

With respect to medicines in the supply chain, Roche has established programs to facilitate the return of unused or outdated products by retailers and others in the supply chain, for incineration.

With respect to unused medicines left over by patients at home, the issue is more complex. Such wastes are typically generated in small quantities across large geographical areas, which make it inefficient and ineffective to collect and manage separately from household trash. In this situation, incineration of household trash, in a state-of-the-art incinerator with heat recovery, and as part of a community's normal waste management process, represents an optimal solution. When incineration is not available, an alternative, environmentally responsible, efficient and effective disposal method should be used, in accordance with local regulations and guidance from competent authorities (e.g. bringing unused or expired medicines back to the pharmacy).

- **Legal SHE requirements:** Roche's policy is to comply with all legal requirements wherever we do business. Compliance with the relevant SHE laws is a minimum requirement, and many of our programs and processes go beyond basic legal obligations.
- **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, which

⁸ http://www.roche.com/dam/jcr:a60949c1-9b92-4a39-a8ff-edcfe6da52f3/en/position_waste_management.pdf

include SHE-related information such as hazard data and waste disposal guidance, are accessible both internally to our employees, and externally via the internet⁹ to the public to ensure transparency. We also conduct testing to determine the composition of liquid waste from diagnostic equipment, and make the results available to employees, customers and the public.¹⁰

- **Audits to support Product Stewardship:** As part of our governance system, we regularly perform SHE audits of our own business activities, our supply chain, and of other service providers (e.g., waste vendors and contract manufacturing organizations) throughout the world. We expect that our suppliers will meet the same high SHE standards established for our internal sites, and we check their performance through audits at their facilities. If suppliers do not deliver to our expectations or are not willing to improve, we stop doing business with them.
- **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 partner them as we strive to continuously reduce our environmental footprint.

Further information

- 1) Roche position papers on several safety, health and environmental topics:
http://www.roche.com/sustainability/how_we_work/positions_policies_downloads.htm
- 2) OECD, Extended Producer Responsibility: <http://www.oecd.org/env/tools-evaluation/extendedproducerresponsibility.htm>
- 3) Paul Anastas and John Warner, 'Green Chemistry: Theory and Practice', Oxford University Press, New York, 1988
- 4) American Chemical Society Green Chemistry Institute Pharmaceutical Roundtable;
<https://www.acs.org/content/acs/en/greenchemistry/industry-business/pharmaceutical.html>
- 5) International organizations on Product Stewardship:
 - a. Global Product Stewardship Council:
<http://www.productstewardshipcouncil.net/>
 - b. The Product Stewardship Society: <http://www.productstewards.org>

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http://www.roche.com/sustainability/what_we_do/for_communities_and_environment/environment/global_product_strategy_and_safety_data_sheets.htm

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https://www.gdch.de/fileadmin/downloads/Netzwerk_und_Strukturen/Fachgruppen/Umweltchemie_OEkotoxikologie/mblatt/2016/b4h216.pdf

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