

EFPIA response to Commission's Sustainable Chemicals Strategy roadmap

Sustainable solutions which are resource-efficient, circular and climate-neutral, are a key value driver for EFPIA. Our member companies are committed to making a positive impact on the lives of patients while operating sustainably, and in particular to transition to a more circular economy with changes throughout the value chains, from product design to new business and market models, from new ways of turning waste into resources, prolonging life of products and to new models of customer behaviour.

EFPIA supports the Commission's need to develop a strategy and to promote research & development for the sustainable transformation of the chemical industry and the creation of green and sustainable manufacturing capacity in Europe. We welcome that the Commission recognises the essential use of chemicals in the production of pharmaceutical products, which are critical to the health of society.

EFPIA's goal is to drive innovative, evidence based and sustainable chemicals management for our industry & society in Europe, while safeguarding access to innovative medicines for patients.

The pharmaceutical sector

The area of pharmaceuticals is one of the most regulated sectors in Europe & the world, with e.g. pre-approval of manufacturing plants, clinical trials and marketing authorisations. Therefore, activities that involve chemicals, necessary for the research and manufacturing of innovative medicines, are required to also pass through strictly regulated pharma processes and this should be considered when implementing & interpreting some elements of chemical legislation. The use of instruments like the Risk Management Option Analysis (RMOA) are essential to evaluate appropriate risk management measures before considering the integration of chemicals, which are critical in innovation, authorization and restriction processes. Due to the global operation of our companies and increasing number of countries with emerging chemical legislation, it is crucial collaborations take place between industry and regulators globally.

In the pharmaceutical sector there are many compounds designed to interact with the endocrine system of patients. As for all pharmaceuticals, the assessment of these compounds is based on an extensive characterization of their primary & secondary pharmacology, followed by studies of their toxicity. As for any active substance, the principles of risk-benefit assessment apply, and "endocrine active" substances present are intended to result in beneficial effects in patients. Likewise, other properties such as toxicity or persistence may also be necessary for an efficacious medicine & these are considered, in total, during the regulatory review process.

Innovation through collaboration

We support measures to foster research into the feasibility of greener products, and industry has been increasingly developing greener manufacturing methods bearing in mind that the safety and efficacy of the medicines we produce must remain the primary objective.

Public private partnerships are important drivers in the innovation of sustainable chemicals. IMI's CHEM21 project dealt with the sustainability of drug manufacturing processes, aiming to reduce the industry's carbon and environmental footprint. It generated a range of methods to make the drug development process more environmentally friendly and developed a metrics Toolkit to measure the sustainability of chemical and biochemical reactions.

While highlighting that 76% of the active pharmaceutical ingredients used in the manufacture of innovative medicines in Europe are sourced in the EU, EFPIA welcomes dialogue with policy makers on how to best

address calls for strategic resilience and global interdependencies of supply chains, while supporting the Commission's zero pollution ambition for a toxic-free environment.