EFPIA Considerations of the Essential use concept

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EFPIA represents the innovative biopharmaceutical industry in Europe, and is responsible for the development, manufacture, and supply of medicinal products in the EU. Medicinal products have a unique value to public health and society at large. They are vital for people's wellbeing, either to manage serious conditions such as cancer, diabetes, bacterial infections, cardiovascular diseases, auto-immune conditions, or to prevent illness and manage symptoms that allow everyone to carry on with their lives.

We welcome the Communication published by the European Commission on 22 April 2024 which aims to avoid and prevent the harm caused by hazardous chemicals to human health and the environment. We share the objective of lowering societal costs associated with diseases and environmental pollution remediation, whilst promoting innovation for non-toxic material cycles and to achieve a clean circular economy. Moreover, EFPIA also supports the designation of use of certain substances as essential for society, notably for health protection.

Description of uses "necessary for health or safety"

Under table 2 of section III.b of the Communication, it is specified that "'Illness and similar health conditions' are conditions that negatively impact quality of life and daily function, and/or is burdensome in symptoms and treatments."[1] The use of this definition for the 'Essential use' concept raises specific concerns for our industry. The phrase "illness and similar health conditions" was taken from an article in the scientific literature on palliative care, and we are concerned that the use of the most harmful substances would only be justified to treat severe illness. **Once legally binding, this concept should not link the use of the most harmful substances to the severity of an illness.** It is indeed critical to maintain a continued supply of chemicals for pharmaceutical uses, regardless of the disease severity.

Additionally, the Communication states that "the necessity of using a most harmful substance to prevent, monitor or treat illness and similar health conditions, should be carefully considered because the use itself could generate adverse effects to human health or the environment". It is important to note that the approval of manufacturing and packaging processes is part of the marketing authorisation granted for medicinal products. These processes occur in controlled industrial settings, where any use of harmful substances is regulated by workplace and environmental protection legislation.

[1] European Commission, Directorate-General for Environment, Bougas, K., Flexman, K., Keyte, I., et al., Supporting the Commission in developing an essential use concept: final report, Publications Office of the European Union, 2023, https://data.europa.eu/doi/10.2779/529713.

Key stakeholder involvement in the decision-making process

In our view, **only medical professionals should determine which medicines are necessary for the health or safety and criticality for the functioning of society.** This includes national or European stakeholders – governments, regulatory authorities e.g., the EMA (European Medicines Agency) or National Competent Authorities (NCAs). The EMA must be part of any decision-making process which determines whether harmful chemicals used in the manufacturing and packaging of medicinal products are necessary for manufacturing medicines for treating all health conditions.

This concept could eventually become legally binding, for instance, through the REACH regulation. However, the ECHA scientific committees and the Commission's REACH Committee currently do not contain representation from the EMA or national health authorities. **Consequently, an 'Essential use' concept could complicate decision-making in the EU chemicals legislation landscape.** In addition, recital 111 of REACH notes that the REACH Regulation should otherwise be without prejudice to the competence conferred on the EMA. Any further expansion of REACH provisions into the medicinal products regulatory domain will create conflict between the missions of ECHA and the EMA.

Our ask

EFPIA requests a more focused discussion with the Commission's DGs (ENV, GROW, SANTE) and the EMA to outline how the 'Essential use' concept will be applied to harmful chemicals used in development, manufacturing, packaging and distribution of medicinal products. We hope that once applied in the REACH revision (or other legislative acts), this concept will lead to a future-proof regulatory framework that does not have any adverse impact on the development, manufacture, and supply of medicinal products in the EU.