European Federation of Pharmaceutical Industries and Associations

Innovation and Regulatory Flexibility to achieve Climate, Environment and Sustainability Goals

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Introduction

Currently, many changes to medicines and their supply chains are being driven by environmental, chemical, food and climate legislation, developed without consideration of how these can be introduced into medicinal products supply to ensure patients' access.

Flexibility and support for innovation in the (re)development and supply of medicines to address climate, environment and sustainability targets should be a priority goal for EU medicines regulators.

Reducing the environmental impact of medicinal product development and manufacturing is an important area of low-carbon innovation and pollution control. Changes to products, their supply chains and manufacturing processes to reduce the Global Warming Potential (GWP) and/or impact on the environment can be achieved through innovation.

Many companies are actively implementing sustainability and environmental programs for medicinal products. Examples include establishing CO_2 reduction targets, switching to alternative energy sources, use of recycled or PVC-free materials in packaging or devices, recycling of solvents, changes to use of plastics and chemicals, reduction in Per- and polyfluoroalkyl substances (PFAS) use, the replacement of F-gases of high GWP in inhalers, cross-industry solutions for recycling materials through take-back schemes, new Tachypleus Amebocyte Lysate/Limulus Amebocyte Lysate (TAL/LAL) endotoxin tests or introduction of new green synthetic chemistry.

It is vital to ensure that critical medicines of high quality remain available to patients globally during any transition period. Although innovation in medicinal products is a priority for regulators and legislators, the drivers of climate, environment and sustainability are not currently among their priorities.

Of critical importance is that much of the change is being driven by environmental, chemical, food or other legislation, developed outside of the framework of the pharmaceutical legislation and considerations for medicinal products. Commission activities and frameworks such as the EU Green Deal[1], and the Chemical strategy for sustainability[2] are developed without full involvement of DG Santé or the EMA, for whom these topics do not currently present a priority area.

Ensuring the availability of safe, efficacious, and high-quality medicines remains the paramount goal of industry and regulators. In order to continue to ensure this, EFPIA believes that following steps should be taken by the Commission and EMA:

- Use of the principles defined in the PRIME/Quality toolbox to enable changes and innovation in the design of new sustainable and environment/climate-friendly products and supply chains, employing appropriate considerations of benefit/risk. This to include:

[1] https://commission.europa.eu/strategy-and-policy/priorities-2019-2024/european-green-deal_en
[2] https://environment.ec.europa.eu/strategy/chemicals-strategy_en

  - Use of alternative Quality evidence in dossiers (e.g. to support specifications for materials, simplified process validation PPQ, control strategies, stability etc)
  - Establishment of priority procedures to enable the overall development plan and regulatory strategy for product changes and to facilitate quicker access for patients to the new medicine (e.g. access to rapid scientific advice, early appointment of rapporteurs)
  - Procedures for rapid, collaborative scientific advice on changes related to sustainability, climate and the environment
  - Potential for accelerated assessment at the time of an application for related variations or product line extensions

- Design of future EMA guidance with innovation to support environment, climate and sustainability goals in mind (considering areas such as the EU variations framework, the pharma legislation, to ensure that innovation is not disincentivised).
- Development of specific Q&As/guidance to support innovators in development and rapid industrialisation of new products or supply chains to meet environmental, climate and sustainability goals (e.g., providing general guidance on-post approval changes to products including any requirements for changes and the use of comparative in-vitro data).
- Collaborative development between industry and regulators of general tools/examples such as PSA (Parallel Scientific Advice) and PACMPs (Post-Approval Change Management Protocols) to enable changes to products manufacturing processes etc.
- The adoption of innovation in support of sustainability and low GWP products as a priority for the new EMA Quality Innovation Group and Innovation Task Force.

Overall, industry believes that support for innovation in the development, commercialisation and supply of products with lower environmental and climate impact should be seen as a **mission-critical priority by EU regulators** (particularly DG Santé and EMA) and enshrined as a goal to support patient access and global climate targets.