

## **EFCG welcomes the publication of the Critical Medicines Act (CMA) and calls for further action.**

The CMA promised to be a game-changer in addressing severe recurrent shortages of critical medicines, relying on a local, robust and sustainable industrial footprint. While it fulfils on most of its promises, it still lacks clarity and focus as to the concrete measures needed to reverse the current predicament.

In October 2023, several EU Member States and Members of the European Parliament, civil society associations and industry stakeholders have called for the strong measures needed to address the recurrent medicines shortages and guarantee EU citizens access to their medicines. The Act presented on March 11<sup>th</sup> by EU Commissioner Oliver Varhelyi recognises the urgency of tackling the root causes of shortages and reducing dependencies, and proposes a set of measures to address them.

As the representative of EU manufacturers of Active Pharmaceutical Ingredients (APIs) and intermediates, EFCG welcomes the measures proposed in the Act to support investments in innovative and environmentally friendly manufacturing processes in the EU. However, the proposal lacks the dedicated EU Critical Medicines fund that would support the needed investments in strategic projects as well as the State Aid mechanisms that will support the corresponding business cases.

We also welcome the changes proposed in the public procurement rules, moving from price-only to criteria based on local, resilient and sustainable production. The disparities in regulatory requirements create an unbalanced global playing field to the disadvantage of EU-based manufacturers. We urge the EU authorities to consider adding **concrete and enforceable** criteria that take into account the vast divergence in environmental and manufacturing standards between EU and third country suppliers. EU standards should become the requirements that all pharmaceutical manufacturers must abide by, regardless of their geographical location.

The API manufacturing industry is the backbone of the pharmaceutical supply chain, thriving on technological innovation and manufacturing excellence. Although the Act recognises the pivotal role of APIs in the supply chain of medicines, it does not go far enough in addressing the competitiveness gap faced by the EU industry.

**EFCG director Maggie Saykali added: “A strategically autonomous and resilient manufacturing base is especially vital in the current complex geopolitical landscape. We call on the Parliament and the Council to implement bold and coordinated measures at the EU level to achieve the strategic objective of securing critical medicines by reducing dependencies, closing the competitiveness gap with other world regions and supporting the EU industrial footprint.**



**Note to editors:**

**EFCG**, The European Fine Chemicals Group, a sector group of Cefic, represents the European manufacturers of Fine Chemicals, Intermediates and Active Pharmaceutical Ingredients (APIs).

Our vision is to help create a world where access to safe and good quality nutrients and innovative medicines is guaranteed for all. We promote a fairer and safer environment for future generations and we champion sustainable processes and enforced regulations that deliver safe products and enhance growth, employment and environmental performance.

**For more information please contact:**

Maggie Saykali, EFCG Director  
msa@cefic.be.

**About Cefic**

Cefic, the European Chemical Industry Council, founded in 1972, is the forum of large, medium and small chemical companies across Europe, which provide 1.2 million jobs and account for approximately about 13% of world chemicals production.