

## Addressing the acute and complex issue of medicines shortages

### Background

Medicines shortages are increasingly becoming an acute issue, putting undue strain on healthcare professionals and endangering the well-being and life of patients throughout Europe.

These shortages – if not properly addressed - are likely to worsen with time. As an essential part of the pharmaceutical value chain, the European API (Active Pharmaceutical Ingredients) producers, represented by EFCG, are actively looking for solutions that can address the root causes of this issue, throughout its complex global supply chain, and set a contingency plan.

### Issues

Supply Chain issues play a major role in the unavailability of pharmaceutical products. The main issues to be addressed are:

1. **Massive offshoring** of API production and RSMs (Registered Starting Materials), leaving the EU dependent on China and India for close to 80% of its medicinal products,
2. **Unexpected closures** of several production units in China - due to either serious accidents<sup>1</sup> or the enforcement of new environmental laws – causing severe shortages,
3. **Procedural delays** in the implementation of changes and improvements to processes.

### Our proposal

We urgently need to prevent further drug shortages by means of proactive and structural actions:

1. **Setting up a fast-track approval for alternate RSMs<sup>2</sup>**: we believe this is urgently needed in order to prevent shortages due to unforeseen events - environmental

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<sup>1</sup> cf. appendix 2 for recent examples

<sup>2</sup> Proposed fast track options are detailed in appendix 3

## EFCG briefing paper

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pollution, natural disasters, quality-motivated recalls or closure of some overseas production facilities to name but a few,

2. Encouraging the maintenance of the European Medicines Agency database of drug shortages and promoting communication between member states health authorities on this topic.
3. Implementing a five to ten-year plan to encourage Research and Development into critical raw materials or technologies produced in Europe, with the aim to reduce the EU's dependency on overseas supplies.

### Conclusion

EFCG considers that **the availability of vital medicines is every European patient's fundamental right** and we believe that the current and future critical shortages interfere with this fundamental right. EFCG's members play a fundamental role in the pharmaceutical supply chain and want to restore the balance of this chain through the mitigating actions proposed above and seek the support of the European Union's health and trade authorities to help them achieve their mission.

### About EFCG

EFCG was formed in 2004 to be the focus, the forum and the voice of the European fine chemicals and Active Pharmaceutical Ingredients manufacturers. We are a non-profit international sector group within Cefic - the Brussels-based European Chemical Industry Council.

EFCG represents over 100 organisations with over 200 manufacturing sites.

For more information please contact:

Maggie Saykali  
Director – Specialty Chemicals  
Cefic aisbl  
+32 2 4369470 or [msa@cefic.be](mailto:msa@cefic.be).  
<https://efcg.cefic.org>

#### About Cefic

Cefic, the European Chemical Industry Council, founded in 1972, is the voice of large, medium and small chemical companies in Europe, which provide 1.1 million jobs and account for 15% of world chemicals production

