

Addressing the acute and complex challenge of medicine shortages

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

These shortages - if not properly addressed - are likely to worsen with time. As an essential part of the pharmaceutical value chain, European active pharmaceutical ingredient (API) producers, represented by EFCG, are diligently looking for solutions to address the root causes of this challenge and develop a contingency plan.

Challenges

Disruptions to supply chains play a major role in the unavailability of pharmaceutical products for reasons including:

- **Massive offshoring** of API production and registered starting materials (RSMs), leaving the EU dependent on China and India for close to 80 per cent of its medicinal products.
- **Unexpected closures** of several production units in China - due to either serious accidents or the enforcement of new environmental laws.
- **Procedural delays** in the implementation of changes and improvements to processes.

Our proposal

We have a three-part solution to prevent further drugs shortages.

1. **Develop a fast-track approval for alternate RSMs.** We believe this is urgently needed to prevent shortages due to unforeseen events, including: environmental pollution, natural disasters, quality-motivated recalls and closures of some overseas production facilities.
2. **Better maintain the European Medicines Agency (EMA) database of drug shortages.** This would involve promoting communication between the health authorities in Member States.
3. **Launching a 5- to 10-year investment plan** to bring critical off-shore technology back to Europe and develop Research and Development into critical raw materials or technologies produced in Europe. These measures will help reduce the EU's dependency on overseas supplies.

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Access to vital medicines – a fundamental right

EFCG believes that access to vital medicines is every patient's fundamental right in the European Union. The current and future critical shortages interfere with this right.

Our members play a fundamental role in the pharmaceutical supply chain and want to restore the continuity this chain with the three-step proposal above. We seek to support the European Union's health and trade authorities to achieve their mission.

About EFCG

EFCG was formed in 2004 to be the focus, forum and 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.

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About EFCG
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