

PRESS RELEASE

Active Pharmaceutical Ingredients manufacturers address critical medicines shortages leaving Europeans and Americans vulnerable and dependent on Asian supplies

Brussels, February 10th, 2020. Active Pharmaceutical Ingredients (API) manufacturers express their concerns and urge EU and US authorities for action as the Coronavirus outbreak in China further highlights the vulnerability of the pharmaceutical supply chain.

Throughout the last year, the European API producers, represented by EFCG, and U.S. manufacturers represented by BPTF, have been alerting regulatory authorities about worsening medicines shortages, actively engaging with them and relevant stakeholders to propose urgent action to alleviate their consequences to our health system. The complex causes and possible solutions to this problem have been detailed in EFCG's recent [position paper](#)¹.

The manufacturing of APIs and Registered Starting Materials plays an indispensable role in the medical supply chain. Meanwhile these essential building blocks have been massively offshored to Asia over the last 20 years, leaving Europe and the US to face shortages and largely dependent on imports from China and other parts of Asia. For some generic medicines, over 80% of the registered starting materials are produced overseas leaving Europe and the US vulnerable to any incident that may disrupt the supply chain. Ensuring continuity in the manufacturing of APIs is essential to address drug shortages.

EFCG and BPTF encourage Authorities to take precautionary actions, such as setting up a fast-track approval for alternate Registered Starting Materials (RSMs) and APIs and actively reinforcing the pharmaceutical supply chain in the West, guaranteeing its competitiveness and supporting the industrialisation of innovative processes.

Says Luis Gomes, Chairman of EFCG's Pharmaceutical Activities Committee: *"The recent outbreak of the coronavirus in China has seen the Chinese authorities taking appropriate steps to introduce quarantine measures to contain the spread of the virus. We support this responsible approach. However, the situation also illustrates the risks of becoming overly dependent on supplies from specific geographies. The current restrictions on logistics, transportation and movement of workers imposed have the potential to significantly exacerbate the existing shortages. The heightened demand can cause further disruptions in the availability of essential medicines such as antibiotics."*

Were this epidemic to develop into a global pandemic, most countries will face shortages of essential medicines at a time where they would need them the most. The dominant position of Asian suppliers and the concentration of API and starting materials sources in this region of the world puts other regions, including the U.S., Europe and Japan in the untenable position of having no alternatives for their most essential medicines.

EFCG and BPTF consider that the availability of vital medicines is every patient's fundamental right and believe that the current and future critical shortages impact this right. EFCG and BPTF members play a fundamental role in the pharmaceutical supply chain and want to secure the supply chain through pragmatic mitigating actions. They are actively working with the European Union and U.S. authorities and other relevant industry stakeholders to bring a timely solution to this urgent problem.



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.

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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.
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About BPTF

The Bulk Pharmaceuticals Task Force (BPTF) is a U.S.-based association for manufacturers of active pharmaceutical ingredients, excipients, and pharmaceutical intermediates. The Task Force's primary objective is to seek clarification of current regulatory requirements and to interact with government agencies on emerging issues that may impact members. BPTF's membership includes manufacturers with foreign as well as domestic facilities, and both large and small business entities.

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ⁱ EFCG position paper available [here](https://efcg.cefic.org/publication/addressing-the-acute-and-complex-issue-of-medicines-shortages/) : <https://efcg.cefic.org/publication/addressing-the-acute-and-complex-issue-of-medicines-shortages/>