PRESS RELEASE – July 2021

Joint statement by EFCG and BPTF on addressing the challenges of the pharmaceutical supply chain

Strategic autonomy of the pharmaceutical supply chain is essential to the sustainability of patient care in the U.S. and the EU

The existence of generic drugs has helped to counterbalance the cost of more innovative medicines for decades. As the price of generics tends to consistently decline due to administrative cost-containment policies on both sides of the Atlantic, pharmaceutical companies are pushed to seek lower-cost materials and manufacturing, opening the door to potential quality, safety and environmental issues. These in turn weakens the supply chain and can result in drug shortages down the line, leaving patients and health professionals with insufficient supplies of their essential medicines.

The COVID 19 crisis has further exacerbated this structural problem which has been building up throughout the recent decade. The fact that many APIs can only be sourced outside the U.S. and Europe and that the production of some drugs (e.g., injectables) was exited years ago due to low sustainability of margins, left both continents with limited supplies of some specific but vital drugs. These issues have not only caught the attention of Health authorities but they were also amply relayed by the media.

In the past 12 months, this situation has become a growing concern and a priority for the United States administration and the European Commission who both decided that the best way to address it would be to re-shore the manufacturing of essential pharmaceuticals. This is best illustrated by the EU Commission's "New Industrial Strategy: building a stronger single market for Europe's recovery"[1] issued last May and the U.S. White House report on Building Resilient Supply Chains[2] issued this month, in addition to the Pharmaceutical Strategy . These two policies are very similar in their conclusions that it is essential to re-shore the production of critical APIs and drug products respectively in the EU and the U.S. and secure a robust and resilient pharmaceutical supply chain.

Of course, not all supply chains can be relocated nor can the United States or the EU countries produce all the medicines needed for their patients and their healthcare systems, mainly due to the complexity of the pharmaceutical supply chain, the lack of harmonization of regulatory structures and many other industrial reasons including free trade policies. Moreover, healthcare systems differ between the two continents: whilst Medicare, Medicaid, different formularies and three big wholesalers are major components of the U.S. healthcare system, the EU has to deal with 27 different healthcare systems, each using different mechanisms to regulate, acquire and compensate for the expense of necessary drugs.

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[1] https://ec.europa.eu/info/sites/default/files/communication-new-industrial-strategy.pdf and https://ec.europa.eu/health/sites/default/files/human-use/docs/pharma-strategy_report_en.pdf

[2] https://www.whitehouse.gov/briefing-room/statements-releases/2021/06/08/fact-sheet-biden-harris-administration-announces-supply-chain-disruptions-task-force-to-address-short-term-supply-chain-discontinuities/

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The way forward

While incentives and new policies are most welcome to help rebuild resilient supply chains, the BPTF and EFCG strongly believe that the security of pharmaceutical supplies should also be based on closely connected, diverse, high-quality and resilient supply chains based in the United States, Europe and other allied countries. Key components of the supply chain (APIs, excipients and precursors, as well as primary packaging such as vials or capsules) need to be part of a global trade of products which comply with the strictest and highest quality, security and environmental standards. This can be achieved by leveling the playing field with other world regions, among other things through increased surveillance inspections, thus ensuring that quality, safety, security and environmental requirements are globally comparable and well respected. Such a coordinated action would also entail the need to reinforce controls and inspections on non-U.S. or non-EU manufacturing sites.

However, this type of plurilateral agreement -promoted by the authorities- among allies needs time as it requires a cooperative approach to secure the supply chain while ensuring the diversity of supply for the respective patients. Considering closer deadlines, there is an opportunity to reinforce and prioritize the already existing manufacturing sites on both sides of the Atlantic. These existing sites have repeatedly demonstrated their compliance with the most stringent quality, environmental and safety requirements and have kept pharmaceutical supplies running during the worst peaks of the current pandemic. In the short run, tax credits, long-term contracts, promotion of technical innovation and sustainable production as well as increased regulatory efficiency could help to effectively make the pharmaceutical supply chain more robust and resilient and able to respond quickly to future global health care crises or other unforeseen events.

Note to editors:

About BPTF

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

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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