# From global to local – what's needed to transform API supply chains

By Florian Cardon and Marina Guillet


Over the last 20 years, the supply chain for over-the-counter and generic active pharmaceutical ingredients (API) has changed beyond all recognition. Where Europe once dominated, Asia has completely reversed the API production dynamic.

According to a November 2022 Medicines for Europe report, Europe's share of production had tumbled from 53% in 2000 to 25% by 2020. With 56% of APIs originating from India and China, Europe has now become highly dependent on these regions for their supply. Two thirds of the valid Certificates of Suitability of Monographs of the European Pharmacopoeia (CEPs) for APIs are now held by Asian manufacturers according to an EU report by life science industry consulting firm, Mundicare.

The decline of Europe's API production can be traced back to the 1990s. During this period, pharmaceutical companies offshored manufacturing as part of a money-saving strategy.
Weaknesses in the API supply chain existed prior to Covid-19, but during the pandemic these vulnerabilities became brutally apparent. The disruption to global trade led to a shortage of basic drugs across the EU and UK.

> Another concern is the geographical concentration of API production sites. According to Mundicare, these are primarily located in only a few provinces in India and China. During the next pandemic, this will pose a significant risk to the supply of pharmaceutical ingredients. The limited range of manufacturers who can make a particular API brings other risks too. Around 70% of manufacturers focus their efforts on a relatively small portfolio of only 1 to 3 APIs. With a small product portfolio, a substantial portion of the API manufacturer's revenue comes from a limited set of products. This concentration of revenue makes them vulnerable to market volatility. If one supplier goes out of business, it's hard to find another who can plug the gap quickly.

More recently the increase in geopolitical instability, such as the war in Ukraine, has accelerated a rethink across European countries about API production to ensure security of supply. These factors have provided impetus for the recent trend of 'reshoring' – bringing pharmaceutical production back within national borders. However, this shift towards regional suppliers brings its own set of challenges.

"It's really difficult to compete against a Chinese or Indian player with the same technology, says Dr. Andreas Meiser, Partner at Mundicare. "[In the EU] You have higher costs for environment policies, you have higher costs for social policies, you have higher wages. But what you could do is compete against [Asian producers] with completely new technology."

This means investing in economically viable, local alternatives. Meiser continues. "Maybe you have a biotechnology process, which is much cleaner, where you have a higher yield. So it's more cost effective to produce [APIs]. This could be a way to bring at least some of these components back to Europe, because you have a technology advantage."

The situation in the U.S. is similar. A 2021 report by The National Academy of Sciences cited research by Anthony Sardella at Washington University's Olin Business School in St. Louis that showed no manufacturing source exists in the U.S. for more than 83% of the APIs in the top 100 generic medicines. This represents over 90% of all medicines consumed. To begin addressing these issues, a $2 billion investment in biotech and biomanufacturing has been launched through the National Biotechnology and Biomanufacturing Initiative.

However, according to Washington University's Olin Business School, the U.S. does have the capacity to make the most essential drugs. But, most of the capacity is sitting idle due to lower offshore operating costs and labour rates, intense pricing pressure and dependence on offshore sources for raw materials.

Take the manufacture of secondary metabolites as an example. The increasing demand for these high value molecules* is driving the need to produce them at scale in a more controlled and environmentally sustainable way. Currently, they are mainly produced by growing plants in fields which lacks local scalable and sustainable production processes. As Europe and the US look for cost effective ways to re-shore API supply, new bioprocessing technologies may offer a solution that is both localised and cost effective.

On such technology is Samabriva's innovative plant-based platform that could be the answer the pharmaceutical industry needs for high-yield, low cost bioproduction of APIs at scale anywhere in the world.

Samabriva takes production out of the field and into the factory by combining the advantages of plant-based systems (low cost, safe, serum- and animal-free) with traditional bioproduction in large-scale bioreactors. This delivers continuous, reliable and environmentally sustainable manufacture of secondary metabolites all year round, in any location even in high-cost, high-wage countries.

For any manufacturer looking to make their API 'reshoring' a success, new technology that addresses the cost inequalities between the US and EU and Asia by providing sustainable, stable and consistent bioproduction will be increasingly hard to resist. Get in touch to find out more about Samabriva's technology.

*The global botanical and plant-derivative drug market is growing rapidly (at an estimated CAGR of just below 9% between 2018 and 2026) according to Global botanical and plant derivative drug market forecast 2018-2026 – Inkwood Research.