



Case Study | Cortellis Generics Intelligence™

Identifying supply chain vulnerabilities

An examination of the specific APIs produced globally for the U.S. market



Situation

A need for insights into the global supply chain for U.S. generic APIs

Johns Hopkins Bloomberg School of Public Health conducted an independent study, co-funded by a grant from a U.S. government agency, analyzing the competition and vulnerabilities in the global supply chain for U.S. generic APIs. Their findings were published in peer-reviewed journal [Health Affairs](#).

To conduct this analysis the researchers needed access to reliable information on facilities manufacturing generic APIs for the U.S. market and information on the APIs produced by the relevant facilities.

Solution

Detailed and reliable intelligence about API manufacturing facilities

The researchers analyzed data from Clarivate's Cortellis Generics Intelligence database to perform the first systematic examination of the specific APIs produced globally for the U.S. market.

Unique, proprietary API manufacturing data

Cortellis Generics Intelligence has been tracking global API manufacturing activities for more than 25 years.

Our API information is obtained from a confidential network of industry sources, including API manufacturers and their competitors, generic drug manufacturers, agents and traders, and government sources.

Our extensive network of industry contacts is contacted on a regular basis to validate data and provide insights into the markets, and information is updated on a weekly basis as and when it has been validated and verified.

“Monitoring the API supply is crucial to identifying vulnerabilities in the U.S. pharmaceutical supply chain and identifying drugs that could represent potential priorities for domestic production.”

Source: Social, M. et al. 2023 'Competition And Vulnerabilities In The Global Supply Chain For US Generic Active Pharmaceutical Ingredients', Health Affairs, Feb, 42(3), pp 407–415. Available at <https://www.healthaffairs.org/doi/10.1377/hlthaff.2022.01120>

Outcome

Monitoring the API supply is key to identifying vulnerabilities

The study concluded that examining the bottlenecks of generic API production is crucial to identifying supply chain vulnerabilities:

- About a third of APIs were manufactured by a single facility, and another third were manufactured by two or three facilities.
- More than one in every five APIs reflected markets in which current FDA standards would have failed to detect low competition because there were three or fewer API manufacturers despite there being four or more manufacturers of finished generic drugs.
- Generic drug manufacturers need to identify and establish relationships with API suppliers worldwide, as a number of factors can cause disruption in the supply chain, and it takes valuable time to find an alternative supplier. Finished drug manufacturers are generally required to obtain FDA approval if they need to add or change their API supplier, a process that may delay manufacturers' ability to respond to market demands or quality problems.

Build a resilient drug supply chain with
Cortellis Generics Intelligence

Contact our experts today:

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