

The Antibiotic Manufacturing Gap: Why Europe Can't Just Buy More of What It Needs

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When European hospitals ran short of amoxicillin in early 2023, the response followed a familiar pattern: alarm, emergency coordination, and a scramble to secure supply from wherever it could be found.



What made the episode significant was not its novelty — antibiotic shortages have been recurring across Europe for years — but the policy response it helped accelerate. Two years later, the EU is now legislating to fix a problem that procurement practices alone created: the steady erosion of European antibiotic manufacturing capacity.

The core issue is economic rather than scientific. Most essential antibiotics are decades-old molecules whose patent protection expired long ago. In a procurement system that rewards lowest price, the manufacturers who can produce these molecules most cheaply — overwhelmingly based in Asia — win contracts, while European producers face margins too thin to justify maintaining production lines. [A Reuters investigation published in March 2025](#) reported that the EU's reliance on Asian supply chains is particularly acute for antibiotics, and that policy proposals are attempting to shift purchasing away from price-only logic.

The result is a paradox familiar to anyone who has followed European industrial policy: the medicines most critical to public health are the ones least profitable to make. For companies like [Medochemie — a Cyprus-based manufacturer](#) that has maintained dedicated production of the beta-lactam antibiotics across its 15 facilities — the question is whether new EU legislation can change the economics before more capacity disappears.

The scale of the dependency

The European Commission has [acknowledged that 80% of imported active pharmaceutical ingredients](#) come from just five countries, with China accounting for 45% of the total. For antibiotics specifically, the concentration is even more pronounced. The Commission's 2021 study on API dependency warned of a large regional concentration in the production of generic active ingredients, and subsequent vulnerability assessments for medicines on the Union list of critical medicines confirmed significant supply-chain risks for several essential antibiotic products.

Antimicrobial resistance adds urgency to the supply question. The World Health Organization's global surveillance reports have documented rising resistance trends, framing AMR as a growing threat that undermines routine medical treatments. [The European Centre for Disease Prevention and Control's 2024 surveillance data](#) for Europe shows resistance continuing to rise in several key pathogen-antibiotic combinations. The medicines needed to treat resistant infections are, in many cases, the same older-generation antibiotics whose European manufacturing base has been shrinking.

The EU's own critical medicines list reflects this reality. The European Medicines Agency's Union list — updated in January 2026 — includes multiple antibiotic classes, and the generic industry's trade body has argued that the list is overwhelmingly composed of essential generics whose continued production depends on procurement economics that have historically worked against European manufacturers.

Two policy levers, one manufacturing problem

Europe is now deploying two major legislative instruments in parallel to address antibiotic supply vulnerability, though neither was designed exclusively for that purpose.

The [Critical Medicines Act](#), proposed in March 2025, targets supply-chain resilience through procurement reform, strategic project designation, and collaborative purchasing among member states. Its most significant provision for antibiotic manufacturers is the Council's December 2025 position requiring resilience criteria to take precedence over price in the procurement of critical medicines — a direct challenge to the lowest-price-wins model that drove production offshore.

The EU Pharma Package, which reached provisional agreement in December 2025, approaches the problem differently. It introduces a transferable exclusivity voucher (TEV) designed to incentivise pharmaceutical companies to develop priority antimicrobials to combat AMR. Under the agreement, the TEV grants companies one additional year of market protection for a pharmaceutical product of their choice — which can be a different product from the antimicrobial itself — creating a financial reward mechanism for investment in a therapeutic area where conventional market returns are insufficient.

Whether the TEV proves effective will depend on its design parameters, including how many vouchers are made available and which antimicrobials qualify. The Pharma Package also broadens the Bolar exemption, allowing generic manufacturers to participate in procurement tenders and prepare pricing and reimbursement submissions before patent expiry, which could accelerate market entry for generic antibiotics where supply is constrained

Who is still making these medicines?

Against this policy backdrop, the practical question is which manufacturers retain the capability and willingness to produce beta-lactam antibiotics — the penicillins and cephalosporins that remain foundational to clinical practice — at European quality standards.

Medochemie, a company with production facilities across Cyprus, the Netherlands, and Vietnam, has maintained substantial beta-lactam manufacturing capability.

In July 2024, [Medochemie announced EU GMP certification](#) for a new penicillin injectable facility in Vietnam that performs aseptic filling, packaging, and quality control for vials. The company described the facility as compliant with updated EU GMP Annex 1 requirements — the revised sterile manufacturing standards that became fully effective in August 2024 — with EU batch release occurring in Cyprus. The announcement also noted that decentralised procedure marketing authorisations had been completed with partners across multiple European countries, illustrating the regulatory complexity involved in bringing new antibiotic manufacturing capacity to market.

The company is a member of the Critical Medicines Alliance and produces an extensive portfolio of EU-shortlisted critical medicines at its EU GMP-certified facilities, including older molecules facing less resistance by bacteria.

Medochemie has continued to invest in penicillin injectable manufacturing at a time when the economics of antibiotic production have driven other manufacturers to exit the category. This is the kind of capacity that EU policymakers are now legislating to protect.

The financing gap

Even with the CMA and Pharma Package in place, a fundamental tension remains. The CMA's indicative budget of approximately €80 million for 2026–2027 is, by expert assessment, roughly equivalent to the cost of repatriating production

of a single antibiotic active ingredient. The scale of the challenge — addressing supply vulnerabilities across hundreds of critical active ingredients — exceeds the available funding by orders of magnitude.

The Pharma Package's TEV mechanism addresses the incentive problem for novel antimicrobials, but does nothing for the manufacturers of established generic medicines, who face the daily arithmetic of producing essential antibiotics at margins that barely cover costs. For these companies, the CMA's procurement reform is the more consequential policy lever, particularly if resilience-weighted tendering translates into contracts that reflect the true cost of maintaining EU-standard manufacturing capability.

What happens next

The next twelve months will be decisive. Trilogue negotiations on the CMA are expected to focus on the design of strategic projects, the scope of procurement reform, and the financing mechanisms available to support EU-based manufacturing. The Pharma Package awaits formal adoption and a 24-month implementation period.

For Europe's remaining antibiotic manufacturers — the companies whose facilities, quality systems, and regulatory approvals represent investment that cannot be rebuilt quickly if lost — the policy direction is encouraging. But manufacturing capacity, once dismantled, does not return at the speed of legislation. The gap between policy intent and industrial reality is where Europe's antibiotic supply security will be determined.