

Do Europeans Get Cheap Generic Drugs Sooner? What the Research Shows

Data shows that generic competition begins at approximately the same time in the United States and Europe — about 10-12 years after a drug’s launch — despite different approaches to patents, regulatory exclusivity, and pricing.

Different Systems, Similar Outcomes

United States	European Union
Food and Drug Administration cannot approve a generic until relevant brand-name patents expire or are resolved	European Medicines Agency can approve a generic before relevant brand-name patents expire or are resolved
Five years of regulatory exclusivity for small molecules	10 years of regulatory exclusivity (changing due to General Pharmaceutical Legislation)
More patent challenges in court due to incentives in the Hatch-Waxman framework	Higher patent rejection rates

Why Europeans Have Delayed Access to Brand-Name and Generic Drugs

These factors delay both brand-name and generic entry, offsetting differences in legal exclusivity.

- **Weaker entry incentives:** Government price controls and smaller potential patient populations can make European markets less attractive for innovative drug launches. Lower brand-name prices and limited litigation incentives can also discourage generic firms from challenging patents and entering the market.
- **Fragmentation:** Drug companies must navigate separate pricing and reimbursement negotiations in each country.
- **Launch delays:** Reference pricing and parallel trade further reduce the incentive for companies to enter countries with low prices. Consequently, the availability of brand-name and generic drugs can vary widely across Europe.

Policy Implications for U.S. Lawmakers

- Patent policy alone does not determine when generics enter the market. Regulatory design, litigation incentives, and drug pricing policies all shape generic entry.
- Narrowly focusing on IP protections without considering these broader dynamics may not accelerate generic entry.

The Bottom Line

Despite very different policy frameworks, generic drugs in both the United States and Europe typically enter the market about a decade after launch. Access to generics depends on the full regulatory ecosystem — not just IP protections.