

A comprehensive overview of

The EU Regulatory Landscape for Generic Drug Approval

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Introduction: Generic Drugs in the European Union

In the dynamic landscape of pharmaceutical healthcare, generic medicines play a pivotal role in ensuring equitable access to vital treatments and fostering sustainable healthcare systems. A generic medicine is, at its core, an affordable alternative to an original, already-authorized medicinal product, often referred to as the "reference medicinal product" or "innovator product."

The European Union (EU), a supranational political and economic union comprising 27 member states, has established a sophisticated and harmonized regulatory framework to govern the approval of these generic drugs. This robust system is meticulously designed to guarantee that, despite their lower cost, generic drugs meet the same rigorous standards of quality, safety, and efficacy as their brand-name counterparts.

This white paper aims to provide a comprehensive overview of this intricate process, the scientific principles, regulatory pathways, intellectual property considerations and ongoing responsibilities that define the journey of a generic drug from development to patient use in the EU.

Navigating the Generic Drug Approval Process

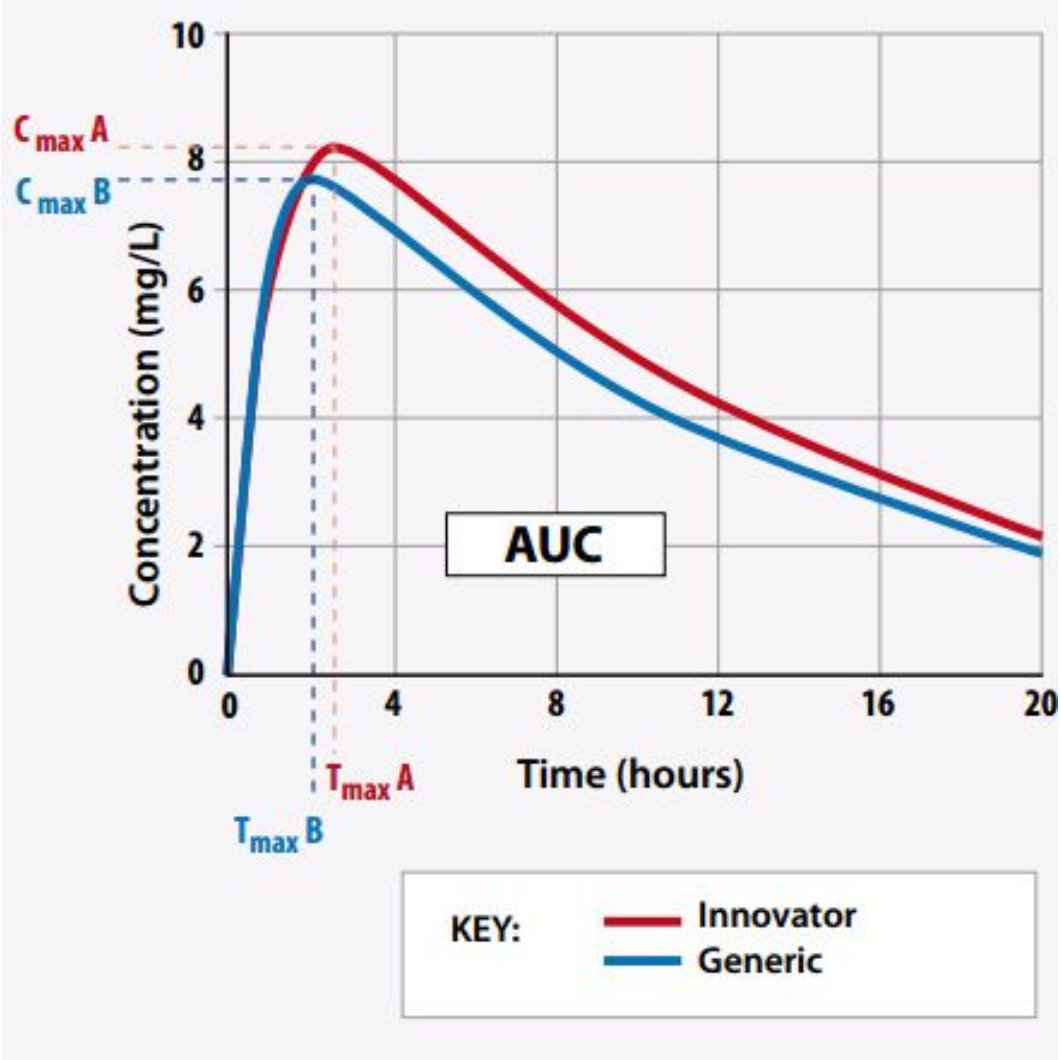
Unlike innovator drugs, which require extensive clinical and pre-clinical data, generic applications rely on different types of independent and interlinked approval pathways. Generic manufacturers can reference the data of the original product, provided they can demonstrate bioequivalence. This streamlined approach facilitates market entry for generics, promotes competition and ultimately provides cost-effective treatment options for patients across all EU member states.

The Scientific Cornerstones: Bioequivalence and Pharmaceutical Equivalence

BIOEQUIVALENCE	PHARMACEUTICAL EQUIVALENCE
• It is the crucial demonstration that the generic drug performs identically to the innovator drug in the body • The drug must be absorbed at the same rate and to the same extent, resulting in the same therapeutic effect • The demonstration of bioequivalence through clinical studies allows the generic to substitute for the original without compromising patient outcomes	• The generic product requires to contain the same active pharmaceutical ingredient (API), in the same strength, dosage form and route of administration as the reference product • Some minor differences in excipients (inactive ingredients) are allowed, but they must not impact the drug's safety or performance

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Bioequivalence Demonstration in Innovator *vs.* Generic Drug



Choosing the Right Regulatory Path for Generics

Manufacturers can choose one of four pathways to seek marketing authorization (MA) in the EU, depending on their strategy

Centralized (CP)
Single application to the EMA for one MA valid in all EU member states

~277 Days

Decentralized (DCP)
Apply in several countries at once where no MA exists

~210 Days

Mutual Recognition (MRP)
Extend an existing national MA to other EU countries

~90 Days

National
Submitted to the NCA for local market approval; it might serve as a foundation for MRP

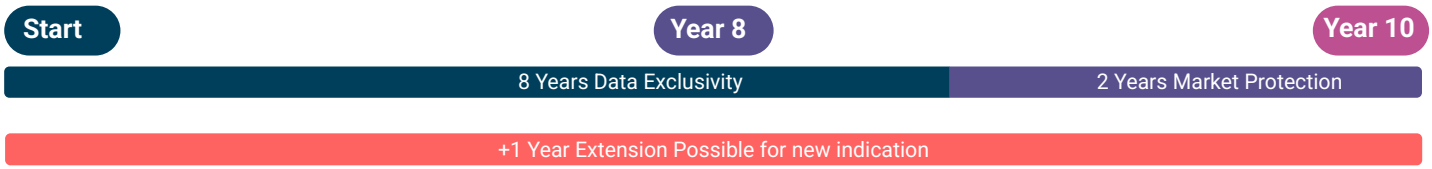
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Intellectual Property and Market Exclusivity: The "8+2+1 Rule"

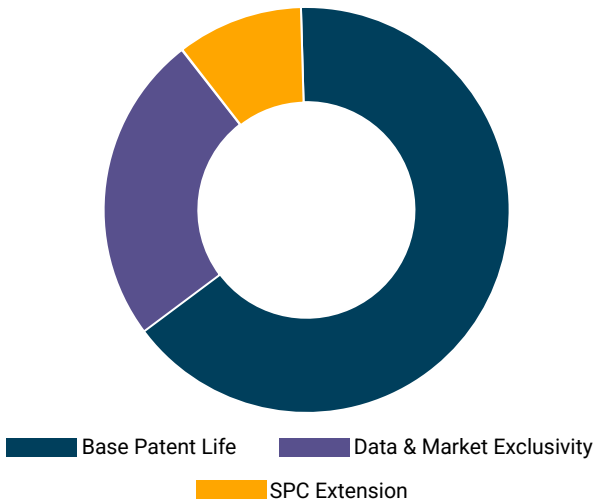
The EU balances innovation and competition with a timeline of protections for the innovator's drug data and market presence



- **Patent Thickets:** Innovator companies frequently create a "patent thicket" around their novel drug inventions. This involves obtaining multiple patents covering various aspects of the drug, such as different formulations, dosages, manufacturing processes, or methods of use. The goal is to create a dense web of overlapping patents that generic manufacturers must navigate or costly and extending the period of exclusivity.

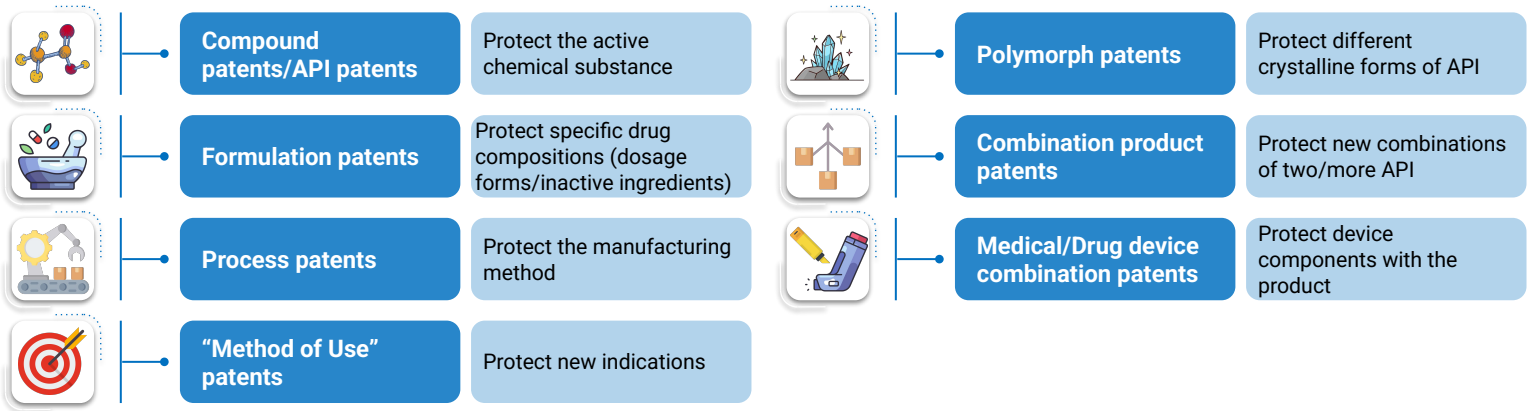
Components of Exclusivity

Innovators can extend market presence beyond the base patent life using SPCs



- **Supplementary Protection Certificates (SPCs):** These are intellectual property rights that extend patent protection for specific medicinal products. The purpose of an SPC is to compensate for the reduction in effective patent life caused by the lengthy regulatory approval process. An SPC can extend the protection of a patent for up to five years. An additional 6-month extension to an SPC can be granted if the innovator complies with an agreed pediatric investigation plan.

Types of Patents

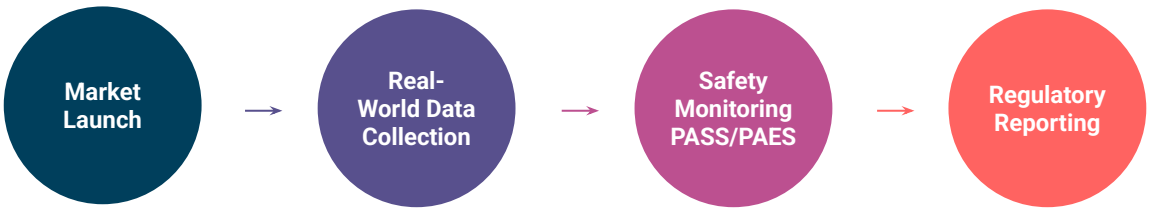


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Post-Authorization Responsibilities: Ensuring Continued Patient Safety

Getting a marketing authorization is not the end. Manufacturers have ongoing responsibilities to monitor drug safety



Conclusion: The Future of Generic Medicines in the EU

The EU's robust regulatory framework for generics effectively balances public health, intellectual property rights, and market access to ensure a reliable supply of safe, affordable medicines. Building on this foundation, the EU has initiated its most significant regulatory overhaul in over two decades, which entered force in 2026 and transitions toward full applicability in 2028. During this implementation window, the framework is actively modernizing to shorten scientific review timelines from 210 to 180 days, streamline exclusivity mechanisms, expand the Bolar provision, and enforce stricter Environmental Risk Assessments (ERAs). As healthcare systems globally seek cost-effective solutions without compromising quality, this evolved framework reinforces the EU's model as an agile, highly sustainable blueprint for generic market entry and long-term patient access.

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