generic medicines

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Generics Market Review

KEY FINDINGS

2025

Generic medicines market review 2025

Key findings overview and policy recommendations

The Generic Medicines Group Market Access Committee is pleased to present the **2025 Market Review: European Generic Medicine Markets Policy overview**.

The purpose of this document is to provide a general overview of the policies that are currently in place for generic medicines in the different European countries, allowing the reader to get a clear understanding.

The 2025 Generic Market Review covers the following policy areas:

1. **Pricing policies**
2. **Budget control mechanisms**
3. **Tendering systems**
4. **Approval timelines**
5. **Governance and stakeholder engagement**

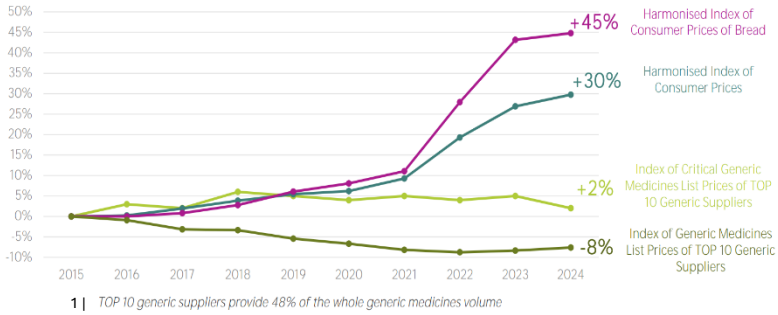
The European countries covered in this edition of the Market Review are Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden and Switzerland.

1. Pricing policies

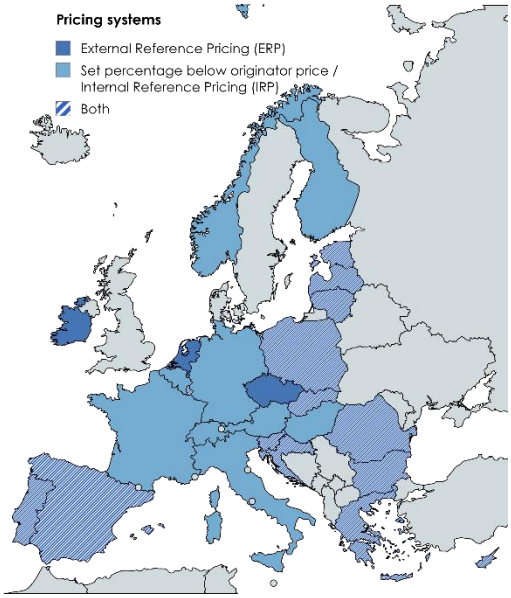
Interplay between current policies leads to unsustainable practices

Key findings

Prices for generic medicines are typically set using ERP/IRP at launch and must be at a mandatory discount from the originator, with further automatic reductions upon entry of the second or third generic competitor. This structure prioritizes short-term cost-containment over long-term sustainability, incentivizing market exit rather than resilience.



1 | *TOP 10 generic suppliers provide 48% of the whole generic medicines volume*



As illustrated in the study graph above[1] , generic medicine prices have stagnated or declined over the past decade, while production costs (e.g., energy, transport, regulatory compliance) have surged by 20–50%.

Price and reimbursement reviews occur regularly, typically every 6–12 months. In the majority of countries (82%), prices for generic medicines are only revised downward once set, and often following reimbursement cuts.

While price increases are theoretically possible, there are no practical or established mechanisms to execute them. In practice, they are exceptionally rare, as they require massive documentation and a process that can take years.

ERP mechanisms using inappropriate benchmarks, are failing to account for inflation, shortages, and regional cost disparities and represent a price erosion automatism.

[1] Based on internal analysis by Teva in the "Generics Health Check" report using data from the following sources: a) IQVIA MIDAS® Quarterly sales data released Q2 2024, Measure: count of products with sales of >0 standard unit, Time Period: MAT Q1 2014 - Q1 2024, reflecting estimates of real-world activity. Copyright IQVIA. All rights reserved. b) Eurostat: Data extracted on 22/10/2024 11:09:48 from [ESTAT], HICP - monthly data (index) [prc_hicp_midx__custom_13408412], All-items HICP and Bread, Index, 2015=100

Central problem

Price and reimbursement systems with the inability to increase prices, even in the context of inflation, regulatory changes, mandatory stockpiling, environmental compliance, or shortages, undermines the economic viability of low-cost generic products. Downward-only pricing makes breakeven points mathematically unattainable and discourages continued supply. This poses a critical systemic challenge, as generic manufacturers manage portfolios of up to 25,000 products, making per-product negotiation unfeasible.

Illustrative examples

In **Slovakia**, price reviews occur every 1 month, but prices cannot be increased, not even when the average of the 3 lowest prices in the EU is higher (ERP condition).

In the **Czech Republic**, certain deregulated ATC groups still require manufacturers to declare a price, which may only be increased once per quarter but decreased monthly.

Interdependencies between reference countries in ERP systems can hinder price increases. For instance, Bulgaria references Slovakia and vice versa, therefore the price level in one country may block adjustments in the other, creating a pricing deadlock.

Policy recommendations

→ Allow **upward price revisions** on a duly justified basis based on transparent criteria (e.g., inflation index, input cost escalation, risk of discontinuation, substantial costs associated with environmental compliance such as those required by the UWWTD, and the remaining number of competitors to ensure a minimum level of supply security).

→ Establish a **simplified arithmetic adjustment mechanism** triggered by objective cost indicators like inflation, energy, transport, workforce cost trends, which include built-in safeguards to mitigate anti-competitive effects and inflationary pressures.

→ **Exclude generic medicines** from **direct External Reference Pricing** (ERP), in line with EURIPID guidelines [2] confirming ERP is most effective when applied to pharmaceuticals without generic competition.

[2] Assessment report of the degree of ERP implementation at the country level, prepared by Agency for Health Technology Assessment and Tariff System (AOTMiT) Attachment_0.pdf

Positive case studies

Germany's ALBVVG law (2023) empowers the Federal Institute for Drugs and Medical Devices (BfArM) to address some supply vulnerabilities directly. Prices for pediatric medicines and critical oncological medicines were temporarily raised by 50%, resulting in higher levels of product availability.

In 2024, an ad-hoc increase was granted for approximately 100 older medicines, that were on the verge of withdrawal in **Greece** due to the continuous price decreases and the extreme clawbacks.

2. Budget control mechanisms

Excessive burden on low-cost medicines

Key findings

Clawback/Payback mechanisms are in place in a 17 out of 30 European countries.

- The majority apply a global pharmaceutical budget cap.
- Few countries apply differentiated clawback/payback to generics, or exempt them from these mechanisms.

Budget overruns are primarily driven by the rising prices of new originator and orphan medicines.[3]

Industry involvement in budgetary planning is limited or absent in most cases.

Central problem

Generic medicines, which already deliver substantial savings, are penalised under broad cost-containment policies. A lack of differentiation means that generics subsidise overspending in high-cost segments.

Illustrative examples

In **Belgium**, the clawback system repeatedly generates overspends in the off-patent sector, as seen in 2024 with an estimated €138 million deficit, prompting legal challenges from industry associations like Medaxes.

Policy recommendations

→ Implement **clawback exemptions** or **lower rates** for generic medicines to ensure their continued sustainability.

[3] 'Trends in Pharmaceutical Expenditure' October 2024 by European Social Insurance Platform (ESIP) and Medicine Evaluation Committee (MEDEV) 2024-10_ESIP-MEDEV-Report_Trends-in-Pharmaceutical-Expenditure.pdf

- → Implement **segmented budget caps**, **differentiated between originator** and generic products, in order to better assess overspend in each category.
- → Ensure transparent clawback methodologies and allow **stakeholder participation** in their design.
- → Introduce **economic sustainability tests** before applying clawbacks to generics.

Positive case studies

In **Estonia**, clawback is based on a contract with the government and is usually related to originators, not generics.

In **Czech Republic**, in general there is no obligatory clawback. In individual cases, especially for highly innovative products under patent protection, an agreement can be reached between the MAH and health insurance companies. These agreements can be part of budget impact analyses and their specific form and amount are determined case-by-case.

3. Tendering systems

Design flaws threaten supply stability and fair competition

Key findings

Almost all countries apply tenders for hospital products, however these are organized at various levels (national, regional, hospital, etc.).

Single-winner tenders are the most common, with 20 out of 27 countries (74%) using them.

Despite MEAT criteria being recommended by the public procurement directive, they are consistently applied only in very few countries, with price being the lead criterion.

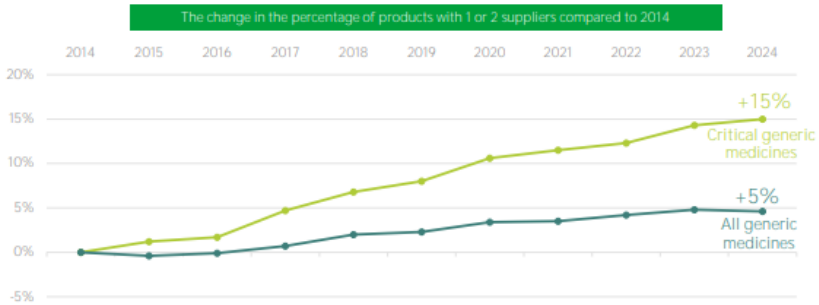
Minimum/maximum volumes are frequently defined, but in practice, they are not guaranteed, and flexibility to adjust volumes mid-contract is often lacking.

The lead time between contract award and first delivery is often short (<60 days).

Industry is frequently not consulted during tender design.

Central problem

Tenders based solely on price, with single winners and no stakeholder dialogue, lead to unsustainable offers, discourage participation, and increase the risk of shortages as the market becomes more and more consolidated.



Between 2014 and 2024, the number of critical generic products with only 1 or 2 suppliers increased by 15%. In the segment of all generic products, this number increased by 5%. 83% of critical generic products are provided by a single major supplier with over 60% volume market share. [4]

Illustrative examples

- In **Spain**, while tenders consider other factors like product characteristics and logistics, the price is still the most valuable factor in award decisions.
- In **Poland**, implementation shows price and payment terms remain the most commonly applied factors.
- In **Belgium**, price remains the primary award criterion. Furthermore, for biological medicines, a royal decree explicitly prohibits the consideration of any elements other than price.

Policy recommendations

Implement the good procurement practices as recommended by the Study on Public Procurement of Medicines for Europe. [5] These include:

→ Make **multi-winner tenders** the (overall) norm, with distributed volumes and enforceable minimum purchase commitments.
→ Incorporate **obligatory non-price award criteria** (e.g., supply reliability, sustainability).
→ Formalize **pre-tender stakeholder consultations** as a standard step in the procurement process.

Positive case studies

- In **Norway**, multi-winner tenders are applied specifically for high-volume market segments.
- In **Portugal**, the tender system awards contracts to multiple winners, typically 2-3 suppliers.

[4] Based on internal analysis by Teva in the "Generics Health Check" report using data from the following source: IQVIA MIDAS® Quarterly sales data released Q2 2024, Measure: count of products with sales of >0 standard unit, Time Period: MAT Q1 2014 - Q1 2024, reflecting estimates of real-world activity. Copyright IQVIA.
[5] "Medicines Procurement Reform: Strenghtening Supply Security through EU Guidance" report (Medicines for Europe) https://www.medicinesforeurope.com/wp-content/uploads/2024/01/Position-paper-proposal-for-EU-procurement-guidelines-Final.pdf

4. Approval timelines

Access delays persist despite regulatory authorization

Key findings

The time from submission to P&R approval for generic medicines varies significantly, ranging from 1 day to 270 days.

Only 7 out of 30 countries meet the ≤30-day approval timeline, while 10 countries (over one-third) exceed the 90 days.

Central problem

While the Bolar exemption aims to deliver access to off-patent medicines on day-1 after expiry of exclusivities, not all countries include P&R activities or tenders within their interpretation. Combined with the fact that tenders are not always re-opened after generics entering the market leads to significant delays in access for patients, as well as lost savings for healthcare systems.

Illustrative examples

In **Slovenia**, approvals can take up to 180 days, significantly delaying patient access.

In **Romania**, there is a 90-day P&R timeline that applies to 95% of generic submissions (those included on the INN list), cases requiring HTA face prolonged 1-2 year processes.

Policy recommendations

→ Set **legally binding timelines** for **national authorities** to **complete** the **P&R process** within a fixed deadline (e.g., ≤60 days) from application submission.

→ **Synchronize tender reopening** with **off-patent entry** to enable generics to compete immediately post-patent.

Positive case studies

In the **Netherlands**, P&R approvals typically occur within one day, allowing immediate market entry.

In **Germany**, P&R approval is typically obtained within 14 days.

5. Governance and stakeholder engagement

Systemic underrepresentation

Key findings

Few countries have formal, regular mechanisms for industry input on budgetary decisions, pricing frameworks, or tender designs.

Where consultations occur, they are often non-binding or limited to public comment without feedback loops.

Central problem

While institutional stakeholders operate with full discretion, effective pharmaceutical policy requires predictable and transparent engagement. Current gaps, including a lack of robust impact studies, reduce policy efficiency and increase risks of unintended consequences.

Illustrative examples

- Industry consultations occur, but are usually non-binding, and feedback is often not acknowledged in final policy decisions.
- Despite multiple policy reforms, generic sector input is not structurally integrated in pricing and budget impact decisions.

Policy recommendations

→ Establish **structured stakeholder forums** for all policy areas impacting market access (P&R, tendering, budget control).
→ Publish **consultation outcomes** and **justifications** for **accepted/rejected proposals**.
→ Include **representatives** from the generic and biosimilar sector in **national medicine policy boards**.

Positive case studies

In **Italy**, it is usual to engage directly with policymakers through appointments with parliamentarians and participation in technical roundtables.

In **Poland**, the national tender procedure incorporates a dedicated consultative stage, allowing stakeholder input that can lead to tangible modifications in the final tender terms and conditions.

Germany installed, specifically for shortages, a standing roundtable in the BfArM with all stakeholders including industry and industry associations, with public minutes.

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