

Reimbursement and Pricing of Pharmaceuticals in Europe

2027

Germany

Preview

Berlin ●

Preview



83.6

Population (in millions)

Source: Eurostat, data for 2025.



7.3

Hospital bed density
(beds per 1,000 inhabitants)

Source: OECD Health
Statistics 2025 (data for
2023).

€

53,500

GDP per capita

Source: Eurostat, data for 2025.

€

4.5

Total GDP (in trillions)

Source: Eurostat, data for 2025.

\$

77.0

68.2

€

Pharmaceutical Market
in 2025 (in billions)

Source: IQVIA, Top 10 Pharmaceutical Markets Worldwide, 2025
(IQVIA MIDAS, MAT December 2025; © 2026 IQVIA). Prices at ex-
manufacturer level; growth in constant US\$. Euro values converted
by IGES at the 2025 ECB average reference rate (EUR 1 = USD 1.1296).

The population of Germany is approximately 84 million. 74.5 million citizens are covered by statutory health insurance (Gesetzliche Krankenversicherung – “GKV”) and approximately 9.2 million are covered by private health insurance (Private Krankenversicherung – “PKV”) including citizens insured via state aid. The aim of this document is to explain the reimbursement system for patients covered by the GKV.

Major Legislation

German laws pertaining to pharmaceuticals are covered by a variety of national laws: The **“Social Security Code V”** (Sozialgesetzbuch V – “SGB V”) regulates drug prescriptions and reimbursement for German citizens insured through public sickness funds. There are a large number of regulations and policies that further define the SGB V. One of the most important laws on reimbursement and pricing of pharmaceuticals is the **“Act on the Reform of the Market for Medicinal Products”** (Arzneimittelmarktneuordnungsgesetz – “AMNOG”).

The **“Medicinal Products Act”** (Arzneimittelgesetz – “AMG”) contains significant provisions for clinical trials, marketing requirements, product safety, pharmacovigilance, information requirements, importation, liability and distribution.

Decision-Makers

The **Ministry of Health** (Bundesministerium fuer Gesundheit) sets the framework for healthcare interventions, approves measures within this framework, monitors the outcome of reforms and controls the functions of the Statutory Sickness Funds. The Ministry of Health also supervises the resolutions and directives passed by the GBA.

The **Federal Joint Committee** (Gemeinsamer Bundesausschuss – “GBA”) is the central decision-making body for pharmaceutical reimbursement for German citizens covered by statutory health insurance. GBA members include the four leading umbrella organizations of the self-governed German healthcare system: the National Associations of Statutory Health Insurance Physicians and Dentists, the German Hospital Federation and the Central Federal Association of Health Insurance Funds. In addition to these four pillar organizations, patient representatives also participate in all the GBA’s sessions and are entitled to express their issues, but are not entitled to vote.

Reimbursement of Pharmaceuticals in Outpatient (Ambulatory) Care

Scope of GKV Benefits and Patient Co-Payments

As a general rule, the GKV solely covers prescription-only drugs. Certain pharmaceuticals, such as life-style drugs (for instance for the treatment of hair loss or obesity) are not covered. Furthermore, the Ministry of Health has drawn up a list of pharmaceuticals which are considered therapeutically inappropriate for reaching the intended medical goals and are therefore not reimbursable. This negative list includes mainly herbal remedies and OTC drugs. OTCs will only be reimbursed for children and adolescents up to the age of 12 and for the treatment of some chronic conditions in adults. Patients have obligatory co-payments ranging from between 7.50 euros and 15 euros for each prescription. Drugs which are priced 20% below the fixed amount (see below) may be excluded from co-payments.

Off-Label Use

Pharmaceuticals prescribed for off-label use are not reimbursable unless the following conditions are met: no authorized product is available for this indication, using it aims at treating a life-threatening disease and scientific data indicates good prospects of treatment success as well as a positive risk/benefit balance.

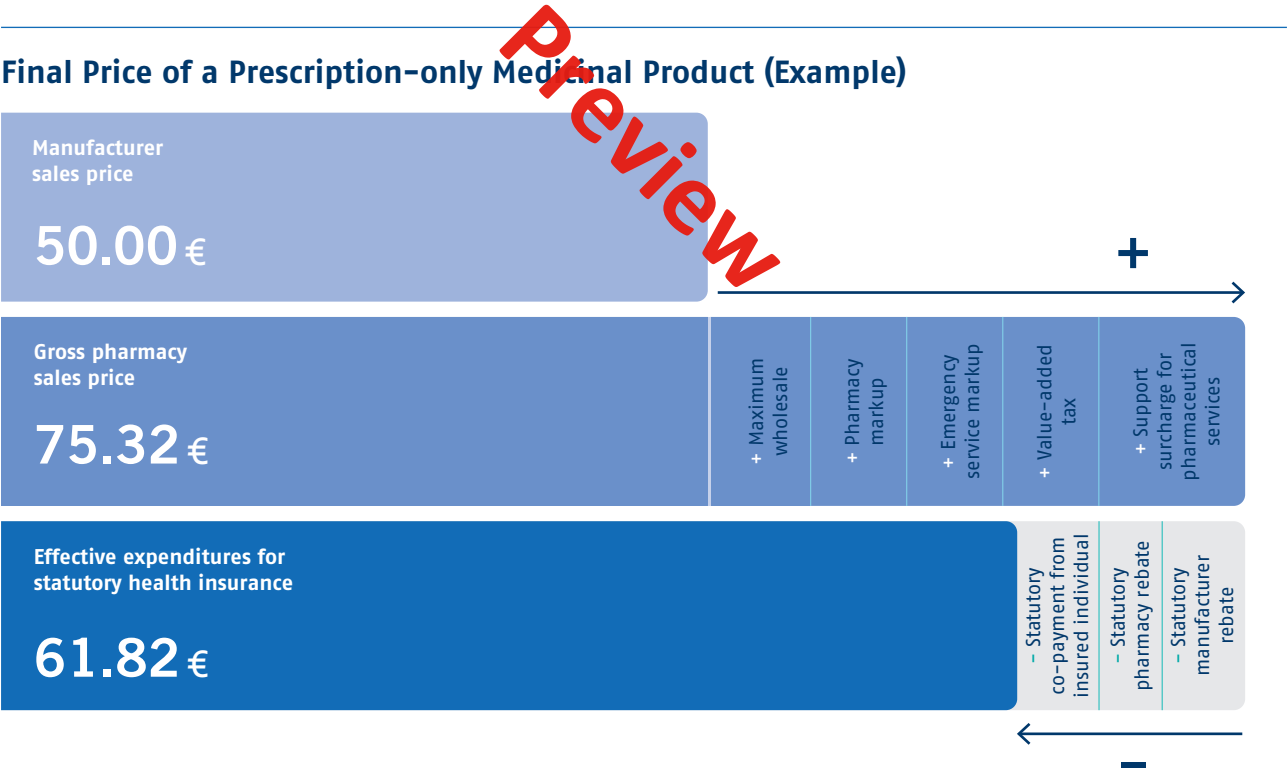
In addition, the GBA may add certain active substances to its so-called off-label use list, making them eligible for reimbursement as well.

Ex-Factory Price

Once a pharmaceutical product has been authorized, it is immediately entitled for reimbursement by the GKV. The initial price for a product with a new active pharmaceutical ingredient can be set freely by the manufacturer for a period of 6 months following market launch. This initial price must be officially declared and subsequently applies to all sales of the product in Germany. After the 6-month period, the price is fixed via the procedures described below. The retail price for prescription-only pharmaceuticals dispensed by pharmacies is fixed. Fixed margins are added to the manufacturer's price which is why prices of every prescription are the same.

Mandatory Rebates

A patient with a prescription for a particular drug can obtain the drug in a pharmacy without having to pay for it. The pharmacist is subsequently reimbursed by the patient's statutory health insurance fund (GKV fund). However, the pharmacist cannot claim reimbursement of the pharmaceutical's entire retail price because mandatory rebates are deducted from the pharmacist's reimbursement claim against the GKV fund. This rule does not apply to pharmaceuticals grouped under certain fixed amount groups (see below). The pharmacist can reclaim manufacturer rebates for patent-protected pharmaceuticals as well as rebates for generics from the pharmaceutical manufacturers. The pharmacist rebate must be borne by the pharmacist.



Source: IGES.

Benefit Assessment of New Pharmaceuticals

As described above, the pharmaceutical manufacturer is initially allowed to set the ex-factory price for a pharmaceutical product for a period of 6 months following market launch. After this period, the reimbursement price is negotiated on the basis of the pharmaceutical product's additional benefit to the patient compared to an appropriate comparative therapy. The early benefit assessment process is mandatory and applies to pharmaceuticals containing new active substances which have been placed on the German market for the first time. By market launch at the latest, the manufacturer has to submit a dossier including authorization documents and results of studies carried out on this product. The additional benefit is evaluated by the GBA. Prices of innovative pharmaceutical products are based on their additional benefit: they are evaluated in the light of the therapy for which they are intended and must demonstrate an additional benefit over the comparative therapies specified by the GBA. The GBA can delegate the benefit assessment to the Institute for Quality and Efficiency in Health Care (IQWiG) or to third parties.

Obligation to Collect Real World Evidence Datas

The GBA can commission the prospective generation of real world evidence (RWE) as part of the benefit assessment procedure for drugs approved for orphan diseases or with a conditional marketing authorization. Reimbursement is thus limited to those providers that participate in the prospective generation of evidence commissioned by the GBA. The generated evidence is evaluated according to a methodological framework published by IQWiG. Only comparative data is eligible for evaluation, and high methodological standards are applied (e.g. transparent quality standards for registers, complete prespecification of the register study and statistical analyses).

Benefit Assessment Evaluation of New Pharmaceuticals Timeframe

Benefit assessment for new pharmaceuticals is a step-by-step procedure between the pharmaceutical company, GKV-SV and GBA.

Pharm. Company	Benefit Assessment			Arbitration Board
	GBA		GKV-SV, Pharm. Company	
	3 MONTHS	3 MONTHS	6 MONTHS	
on market launch at latest		oral hearing		
dossier	early additional benefit evaluation	resolution	negotiation → reimbursement price	
		drug without additional benefit and eligible for fixed-amount group → Transfer to fixed-amount group	drug without additional benefit (but not eligible for fixed-amount groups) and drug with additional benefit	

Source: IGES based on GKV-SV

Exemption of Antibiotics of Last Resort from Early Benefit Assessment

Antibiotics of last resort (also called reserve antibiotics) can be exempt from the German benefit assessment. The manufacturer has to submit a formal request three months before launching the antibiotic. In case of an exemption, antibiotics of last resort are not subject to price regulation. However, hospital antibiotics must undergo the regular procedures for reimbursement in inpatient care.

Price Negotiation

If an additional benefit has been identified, the GKV–SV negotiates a reimbursement amount with the manufacturer in the form of a surcharge on the corresponding comparator therapy. If no additional benefit has been demonstrated, the reimbursement amount must not lead to annual therapy costs higher than those of the corresponding comparator therapy.

Confidential Prices

Previously, reimbursement amounts in Germany were publicly available and were widely used as an international price reference. Effective January 1, 2025, the MFG allows the negotiated reimbursement amount to be treated as confidential, provided that the drug is an innovative medicine being marketed in Germany for the first time and the company can demonstrate corresponding research activities in Germany. Choosing confidentiality entails a mandatory additional discount of 9% on the negotiated amount, and the option is made after the amount is agreed (not before the negotiation). The regulation is temporary: it applies to reimbursement agreements concluded up to June 30, 2028 (sunset clause), and the Federal Ministry of Health must evaluate it by the end of 2026.

Rebate Contracts

Pharmaceutical manufacturers are invited to participate in individual GKV fund tenders in order to conclude rebate contracts in addition to claiming mandatory discounts. Today, rebate contracts cover most generics on the market. They are optional for innovative pharmaceuticals.

A pharmaceutical manufacturer who is awarded a rebate contract for a generic will automatically supply all patients of a particular GKV fund. In other words, pharmacies may only dispense generics

for which rebate agreements are in effect. Software programs guide physicians in prescribing the correct generic, i.e. which is covered by the respective patient's GKV fund rebate contract. Patients benefit from rebated generics as they are exempt from personal co-payments.

When an active ingredient no longer has its patent protection, physicians can either prescribe the original brand, a branded generic or the generic name of an active ingredient. If generic versions of a prescribed active ingredient are available, pharmacists are legally obliged to dispense a generic version (generic substitution = aut-idem-rule). However, if a pharmaceutical product containing the prescribed active ingredient is subject to a contractual rebate agreement between a GKV fund and the marketing authorization holder, pharmacists are obliged to dispense the rebated pharmaceutical.

Orphan Drugs

Early benefit assessment regulations also cover orphan drugs, but some specific rules apply: a full benefit assessment is not required for orphan drugs that do not exceed a turnover of 30 million euros over a 12 month period for GKV patients. Only the extend of their additional benefit has to be proven, based on the assumption that orphan drugs do indeed have an additional benefit. In this case, the pharmaceutical manufacturer only needs to submit a condensed version of the dossier and benchmark the orphan drug's benefits against the comparative therapy from a conclusive phase III trial. However, if a limit of 30 million euros is exceeded, a full dossier is required.

Fixed-Amount Setting in Germany

Fixed amounts refer to the maximum reimbursement limits set by the GBA and the GKV–SV for groups of active ingredients that are similar or therapeutically comparable. In Germany, fixed-amount groups cover most generic drugs as well as patented drugs. Patented drugs are often compared to generic drugs, especially

Who we are

Ecker + Ecker, IGES Pharma and Quantify Research are part of athagoras, a group of specialized consulting companies that supports life science companies on their journey from idea to market launch.

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- Data & AI services
- Security services
- Infrastructure & cloud
- Integration services

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