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PPRI
Pharmaceutical Pricing and Reimbursement Information

PPRI Pharma Brief: Germany 2025

Pharmaceutical Pricing and Reimbursement Information (PPRI) Pharma Briefs Series

Produced by the Pharmaceutical Pricing and Reimbursement Information (PPRI) Secretariat

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This report contributes to the implementation of the 2030 Agenda for Sustainable Development, in particular to Sustainable Development Goal (SDG) 3 "good health and well-being" and its target 3.8: Achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all.

About PPRI Pharma Briefs

This concise report on the pharmaceutical pricing and reimbursement policy framework in Germany is part of the series of PPRI Pharma Briefs launched by the Pharmaceutical Pricing and Reimbursement Information (PPRI) Secretariat in 2019.

PPRI networks

The PPRI network is a collaboration of **pharmaceutical pricing and reimbursement authorities** of 50 - mostly European – countries (as of August 2025) as well as international and European institutions (e.g. European Commission, OECD, World Health Organization). The aim of this network is to facilitate exchange between public officials, supported by scientific evidence and a common understanding of pharmaceutical policy issues. Under the framework of PPRI, further regional PPRI networks (e.g. in Central Asia) and thematic PPRI networks (e.g. on medical devices) have been established. PPRI networks are coordinated by the PPRI Secretariat which is hosted at the Pharmacoeconomics Department of the Austrian National Public Health Institute (Gesundheit Österreich GmbH / GÖG).

PPRI contributes to the international scientific evidence base, in particular in the areas of (comparative) **pharmaceutical systems research** and pharmaceutical policy analysis, by providing country information that is usually not published in other literature. This is of interest for policy-makers who want to learn from other public authorities and countries, for example for the purpose of benchmarking, as well as for researchers who conduct policy analyses and require contextual information on national pharmaceutical systems.

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The series **PPRI Pharma Briefs** responds to the interest and needs expressed by policy-makers and technical experts in public authorities responsible for the pricing and reimbursement of medicines to read concise reports of the pharmaceutical policies in other countries. They are complemented by PPRI Medical Devices Briefs.

The PPRI Pharma Briefs draw upon the information and data that have been provided by the PPRI network members, in addition to literature and relevant documents, such as legal provisions.

For requests and comments, please contact ppri@goeg.at.

Key data at a glance

General and economic data

Population (12/2024)	83.6 million
Country size (2024)	357,700 km2
Gross domestic product / GDP (2023 p.)	GDP per capita: USD PPP 68,019.
Health expenditure / HE (2022)	HE per capita: € PPP 5.317 HE in % of GDP: 12.6% Public HE as % of total HE: 87%
Pharmaceutical expenditure / PE (2022 / 2023)	PE per capita: € 721.- (outpatient sector only, 2022) Public PE as % of total PE: 81% (outpatient sector only, 2022) SHI public PE € 50.17 billion (2023) SHI public PE in % of SHI expenditure: 17.38% (2023)

GDP = gross domestic product, HE = health expenditure, p. = provisional data, PE = pharmaceutical expenditure, PPP = Purchasing Power Parities, SHI = statutory health insurance (Gesetzliche Krankenversicherung / GKV), USD = United States dollars

Sources: population – Statistical Office 2025 [1], country size – Statistical Office 2024 [2], GDP – OECD 2025 [3], health and pharmaceutical expenditure (outpatient sector only) - OECD/European Commission 2024 [4], SHI expenditure – GKV-Spitzenverband [5]

Provision of pharmaceuticals

Community pharmacies (31 Dec. 2023)	17,571 community pharmacies (thereof 4,621 subsidiary pharmacies1)
Dispensing doctors	No dispensing doctors
Wholesale (2024)	9 full-line wholesale companies2
Pharmaceutical industry (2024)	614 companies, with 132,700 staff 48 multi-national companies3

[1] Each community pharmacy is allowed to have up to 3 subsidiary pharmacies
[2] Data relate to member companies of the association of the full-line wholesale companies
[3] Data relate to member companies of the association of research-based industry

Sources: community pharmacies – ABDA 2024 [6], wholesale – PHAGROS 2024 [7], pharmaceutical industry – BPI 2024 [8], vfa 2024 [9]

Pharmaceutical market

Pharmaceutical market (2023)	€ 73.419 billion (solely outpatient market)
Medicines (1/2025)	104,226 medicines authorised (counted including different pharmaceutical forms and dosages), thereof: • 69,864 pharmacy-exclusive medicines (i.e. these medicines must be dispensed in a pharmacy) and 34,362 medicines permitted for sale in non-pharmacy dispensaries • 53,396 prescription-only medicines (all pharmacy-exclusive) No data available on the number of reimbursed medicines (since a negative list applies)
Generic market shares (2023)	17.8% in value (market relating to statutory health insurance prescription-only medicines), expressed at manufacturer price level 80.0% in volume (market relating to statutory health insurance prescription-only medicines), expressed in defined daily doses
Biosimilar market shares (2023)	4.5% in value (market relating to statutory health insurance prescription-only medicines), expressed at manufacturer price level 0.25% in volume (market relating to statutory health insurance prescription-only medicines), expressed in defined daily doses

Sources: pharmaceutical market – Pharma Deutschland 2024 [10]; number of medicines – BfArM 2025 [11], generic market shares – ProGenerika 2024 [12], biosimilar market shares – Probiosimilars 2024 [13]

Pharmaceutical pricing (2025)

Price regulation	Price regulation for medicines funded by the social health insurance (statutory as well as private social health insurance) in the outpatient and inpatient sectors, applicable from month 7 after market launch of the medicine or new indication (note: the regulated price is the reimbursement amount of the public payer) Free pricing for the above-mentioned medicines during the first year (with retrospective pricing for months 7 to 12 after market launch in case of successful negotiations)
Pricing authorities	**Outpatient:** Federal Joint Committee (Gemeinsamer *Bundesausschuss* / G-BA) **Inpatient:** same as for medicines in the outpatient sector
Key pricing policies	**External price referencing:** no (until the end of 2024, legislation provided for considering prices in 15 reference countries in case of failed agreement between the parties) **Value-based pricing:** pricing from month 7 is based on the determination of the Federal Joint Committee (*Gemeinsamer Bundesausschuss* / G-BA) regarding the added benefit, which is informed by an HTA prepared by the HTA institute IQWiG **Price negotiations:** negotiation of the reimbursement price (*Erstattungsbetrag*) between the Federal Association of Sickness Funds (*GKV-Spitzenverband*) and the pharmaceutical company for price-regulated medicines (funded by the social health insurance) in outpatient and inpatient sectors) **Managed-entry agreements:** previously no confidential discounts as result of the price negotiations between the *GKV-Spitzenverband* and the company, but concluded by hospitals and hospital groups as part of their procurement processes; legal permission from 10/2024 to negotiate confidential discounts (under special conditions; see §130b Abs. 1c SGB V) **Tendering**: in the outpatient sector: tendering for active ingredients conducted by sickness funds (so-called "discount agreements"/ *Rabattverträge*); in the inpatient sector: procurement is conducted by hospitals and hospital procurement groups **Cost-plus pricing**: not applied **Generic price link:** not applied **Biosimilar price link:** not applied
Pricing in the supply chain	**Wholesale:** remuneration is regulated for medicines funded by the social health insurance (through two mark-up schemes which contain percentage mark-ups and fixed amounts – one scheme for funded prescription-only medicines and the other scheme for funded non-prescription medicines) **Pharmacy:** remuneration is regulated for medicines funded by social health insurance through a mark-up consisting of flat fee and a percentage mark-up **Value-added tax:** 19% for medicines (same as standard VAT)

Source: for references see main body of the text

Pharmaceutical reimbursement (2025)

Reimbursement authorities	**Outpatient:** Federal Association of Sickness Funds (*GKV-Spitzenverband*) **Inpatient:** no specific reimbursement authority
Reimbursement lists	**Outpatient:** a negative list **Inpatient:** hospital pharmaceutical formularies
Reimbursement criteria	**Outpatient:** guaranteed reimbursement as soon as a medicine with a marketing authorisation is launched in the national market. **Inpatient:** guaranteed reimbursement as soon as a medicine with a marketing authorisation in the national market, no reimbursement decision, procurement decisions for medicines used in hospitals usually based on the hospital pharmaceutical formulary of individual hospitals
Co-payments for medicines	**Outpatient:** a prescription fee of 10% of the pharmacy retail price, but min. € 5.- and max. € 10.- **Inpatient:** no co-payments
Demand-side measures to enhance the uptake of off-patent medicines	**Reference price system:** in place (called "*Festbetragssystem*") **Prescribing by International Non-Proprietary Name (INN):** allowed **Generic substitution:** mandatory **Biosimilar substitution:** for selected medicines (since 3/2024)

Source: for references see main body of the text

Key technical terms are defined in the glossary in Annex 2.

Summary

The German pharmaceutical pricing and reimbursement system has substantially changed with the **AMNOG** (*Arzneimittelmarktneuordnungsgesetz*) in **2011**, which introduced price regulation for medicines funded by the social health insurance (both statutory as well as private health insurance). Major authorities and bodies responsible for pricing and reimbursement in Germany are the Federal Ministry of Health (as the overall legislator), the Institute for Quality and Efficiency in Healthcare (*Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen* / IQWiG), which performs Health Technology Assessment (HTA), the Federal Joint Committee (*Gemeinsamer Bundesausschuss* / G-BA), which is the key decision-making body within the system of joint self-governance and appraises the HTA reports, and the Federal Association of Sickness Funds (*GKV-Spitzenverband*) that negotiates with the manufacturers the reimbursement amount of medicines.

Medicines can be launched in the German market as soon as they have received marketing authorisation. In these early market phases, the pharmaceutical company determines the price, and the expenses for medicines are covered by the social health insurance. As part of the AMNOG system, the pharmaceutical company has to submit a dossier for an **HTA** upon market launch. No HTA is necessary for medicines with annual sales of less than € 1 million. Based on the HTA report by IQWiG (which has to be presented to the G-BA within three months after the dossier has been submitted), the G-BA determines, within another three months, whether the medicine demonstrates an added benefit compared to an appropriate comparator therapy. For orphan medicines (unless those with annual sales of more € 30 million) and for reserve antibiotics, the medicine is assumed to have added benefit, and no HTA is conducted to demonstrate this. In case of a decision on a **granted added benefit**, the **Federal Association of Sickness Funds negotiates with the pharmaceutical company** on the reimbursement amount which aims to reflect the "value" of the medicine. If no agreement is reached, an arbitration board will take the decision based on these considerations. Overall, the AMNOG process lasts 12 months; the negotiated reimbursement amount is applied retrospectively from month 7 after market launch or new indication. Since January 2025, confidential reimbursement amounts may be negotiated between the GKV-Spitzenverband and the manufacturer (Medical Research Law 2024; temporary provision until mid-2028).

The negotiated reimbursement amount also serves as the maximum ex-factory price for medicines used in the **hospitals**, which are procured by individual hospitals or hospital groups. Hospitals may and do also conclude managed-entry agreements with confidential discounts.

A medicine that, according to G-BA appraisal, does not demonstrate an added benefit, can be eligible for negotiated reimbursement based on the most economically appropriate comparative therapy or can be clustered into the **reference price system** (*Festbetragssystem*).

Reference groups are established for medicines of the same active ingredients, of pharmacological-therapeutically comparable ingredients and of therapeutically comparable effect (this is of relevance for combinations of medicines). The G-BA decides on the establishment of a reference group and on clustering medicines into a reference group, and the Federal Association of Sickness Funds (*GKV-Spitzenverband*) calculates the reimbursement amount.

In addition, **for off-patent medicines in the outpatient sector**, sickness funds have been launching **tendering procedures for active ingredients** and they conclude contracts ("***Rabattverträge***") with the successful bidder, which include a confidential price. Individual sickness funds may also negotiate confidential discounts for medicines which have undergone the AMNOG process.

Germany applies a system of **mandatory manufacturer discounts**, whose extent varies depending on the patent status and inclusion of a medicine into the reference price system.

In the outpatient sector, **wholesale and pharmacy mark-ups** are regulated for medicines funded by social health insurance, with different schemes for prescription-only and non-prescription medicines. For reimbursed medicines, pharmacies are requested to grant a mandatory pharmacy discount to the sickness funds. The value-added tax on medicines is 19%, which equals the standard value-added tax.

In Germany, all medicines are reimbursed unless those included in a **negative list** applied in the outpatient sector (e.g., non-prescription medicines except for children under the age of 12, lifestyle medicines). As a rule, insured people pay a **prescription fee** of 10% of the price of a medicine, however the minimum fee is € 5.- and the maximum fee is € 10.- Further patient payments may arise if the insured person insists on being dispensed a medicine included in the reference price system with a pharmacy retail price above the reference price (except for a price difference of 20% and less). Children and chronic patients (on application to the sickness fund) are exempt from co-payments. For medicines used in hospitals, no patient co-payments are charged.

Doctors may **prescribe by** International Non-Proprietary Name (**INN**) on a voluntary basis. **Generic substitution** is **mandatory** in community pharmacies. **Biosimilar substitution** was introduced for selected active substances in March 2024.

The German **AMNOG** system has seen several adjustments and **changes** since its introduction in 2011, with the legal permission for confidential discounts as one of the latest changes from 2025 (Medizinforschungsgesetz – MFG).

Keywords

Pricing, reimbursement, pharmaceutical policies, pharmaceutical system, Germany

Kurzfassung

Von grundlegender Bedeutung für die Organisation des deutschen Arzneimittelpreisbildungs- und -erstattungssystems ist das *Arzneimittelmarktneuordnungsgesetz* **(AMNOG),** das die Preisregulierung für jene Arzneimittel einführte, die von der Sozialversicherung (sowohl GKV / *Gesetzliche Krankenversicherung* als auch PKV / *Private Krankenversicherung*) finanziert werden. Als zentrale Behörden und Gremien rund um die Preisbildung und Erstattung von Arzneimitteln in Deutschland fungieren das Bundesministerium für Gesundheit, das für die Erstellung von Health-Technology-Assessment(HTA)-Berichten zuständige *Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen* (IQWiG), der *Gemeinsame Bundesausschuss* (G-BA) als oberstes Beschlussgremium der gemeinsamen Selbstverwaltung zur Beurteilung der HTA-Berichte und der *GKV-Spitzenverband*, welcher die Erstattungsbeträge für Arzneimittel mit den Herstellern verhandelt.

In Deutschland können die Hersteller Arzneimittel unverzüglich auf den Markt bringen, sobald sie dafür eine Zulassung erhalten haben. In dieser Anfangsphase setzen die Unternehmen den Preis frei fest, dessen Kosten von der Krankenversicherung getragen werden. Im Rahmen des AMNOG-Verfahrens muss der Hersteller unverzüglich nach der Zulassung ein Dossier zur Bewertung einreichen, woraufhin das IQWiG innerhalb von drei Monaten einen **HTA**-Bericht erstellt. Für Arzneimittel mit jährlichen Ausgaben von weniger als einer Million Euro für die soziale Krankenversicherung kann ein Antrag auf Befreiung vom HTA gestellt werden. Auf Basis des HTA des IQWiG beschließt der G-BA innerhalb von weiteren drei Monaten über den Zusatznutzen des Arzneimittels gegenüber einer zweckmäßigen Vergleichstherapie. Bei „Orphan drugs" (Arzneimittel für seltene Erkrankungen) mit einem Umsatz von unter 30 Millionen Euro jährlich und Reserveantibiotika wird der Zusatznutzen als belegt angenommen. Falls **ein Zusatznutzen** festgestellt wurde, **verhandelt der GKV-Spitzenverband mit dem Unternehmen** über den Erstattungsbetrag, welcher den Zusatznutzen des Arzneimittels berücksichtigt. Falls bei der Preisverhandlung keine Einigung erzielt werden kann, entscheidet eine Schiedsstelle unter Berücksichtigung dieser Komponenten. Das AMNOG-Verfahren dauert in Summe 12 Monate; der verhandelte Erstattungsbetrag gilt rückwirkend ab dem 7. Monat nach Inverkehrbringen bzw. Neuzulassung eines neuen Anwendungsgebiets des Arzneimittels. Seit Januar 2025 dürfen unter bestimmten Voraussetzungen vertrauliche Erstattungsbeträge zwischen dem GKV-Spitzenverband und Unternehmen verhandelt werden (Medizinforschungsgesetz – befristete Regelung bis Mitte 2028).

Der verhandelte Erstattungsbetrag gilt auch als Höchstpreis für den **stationären Sektor,** d. h. als maximaler Abgabepreis des pharmazeutischen Unternehmens (ApU) beim Einkauf durch die Krankenhäuser oder Krankenhausverbände. Die Krankenhäuser können in der Folge sogenannte Preismodelle mit vertraulichen Rabatten abschließen und sie wählten diesen Weg auch für einige Produkte.

Falls der G-BA keinen Zusatznutzen für ein Arzneimittel festgestellt hat, können ebenfalls Preisverhandlungen auf Basis der Kosten der wirtschaftlichen Vergleichstherapie durchgeführt werden oder es kann das Arzneimittel in das **Festbetragssystem** aufgenommen werden.

Eine Festbetragsgruppe kann für Arzneimittel mit denselben Wirkstoffen (Stufe 1), für Arzneimittel mit pharmakologisch-therapeutisch vergleichbaren Wirkstoffen (Stufe 2) und für Arzneimittel mit therapeutisch vergleichbarer Wirkung, insbesondere für Arzneimittelkombinationen (Stufe

3), gebildet werden. Der G-BA bildet die Festbetragsgruppen und der GKV-Spitzenverband setzt die Festbeträge fest.

Darüber hinaus führen die **Krankenkassen Wirkstoffausschreibungen für patentabgelaufene Arzneimittel im niedergelassenen Sektor** durch und schließen mit dem Unternehmen, das den Zuschlag erhalten hat, einen sogenannten **Rabattvertrag** ab, bei dem der vereinbarte Preis vertraulich ist. Auch für gemäß AMNOG verhandelte Arzneimittel können die einzelnen Krankenkassen mit den pharmazeutischen Unternehmen nachgelagerte vertrauliche Rabatte vereinbaren.

In Deutschland kommen **gesetzliche Herstellerrabatte** in unterschiedlichen Höhen zur Anwendung, je nachdem, ob es sich um ein patentgeschütztes oder ein patentabgelaufenes Arzneimittel und/oder ein festbetragsgeregeltes Produkt handelt.

Die **Großhandels- und Apothekenaufschläge** sind für Arzneimittel, die von der Sozialversicherung erstattet werden, reguliert, wobei unterschiedliche Aufschlagsschemen für verschreibungspflichtige und nicht verschreibungspflichtige Arzneimittel zur Anwendung kommen. Apotheken sind verpflichtet, den Krankenkassen einen gesetzlichen Apothekenrabatt zu gewähren. Die Umsatzsteuer auf Arzneimittel beträgt 19 Prozent und weist somit den gleichen Wert wie die allgemeine Umsatzsteuer auf.

Im niedergelassenen Sektor Deutschlands werden alle Arzneimittel erstattet, die nicht explizit als Ausnahme definiert sind (diese **Negativliste** umfasst etwa nicht verschreibungspflichtige Arzneimittel, außer für Kinder unter 12 Jahren, und Lifestyle-Produkte). In der Apotheke wird von den Versicherten für jedes verschreibungspflichtige Arzneimittel pro Packung eine **Rezeptgebühr** von 10 Prozent des Verkaufspreises, allerdings höchstens 10 Euro und mindestens 5 Euro, eingehoben (Zuzahlung). Darüber hinaus können Aufzahlungen anfallen, falls eine versicherte Person auf einem Arzneimittel mit einem Verkaufspreis über dem Festbetrag besteht (Arzneimittel mit einem Preisunterschied von bis zu 20 % zum Festbetrag können von der Aufzahlung ausgenommen werden). Kinder und chronisch kranke Patientinnen und Patienten sind (auf Antrag bei der Krankenkasse) von Zuzahlungen befreit. In Krankenhäusern fallen für die Patientinnen und Patienten keine Zahlungen für Medikamente an.

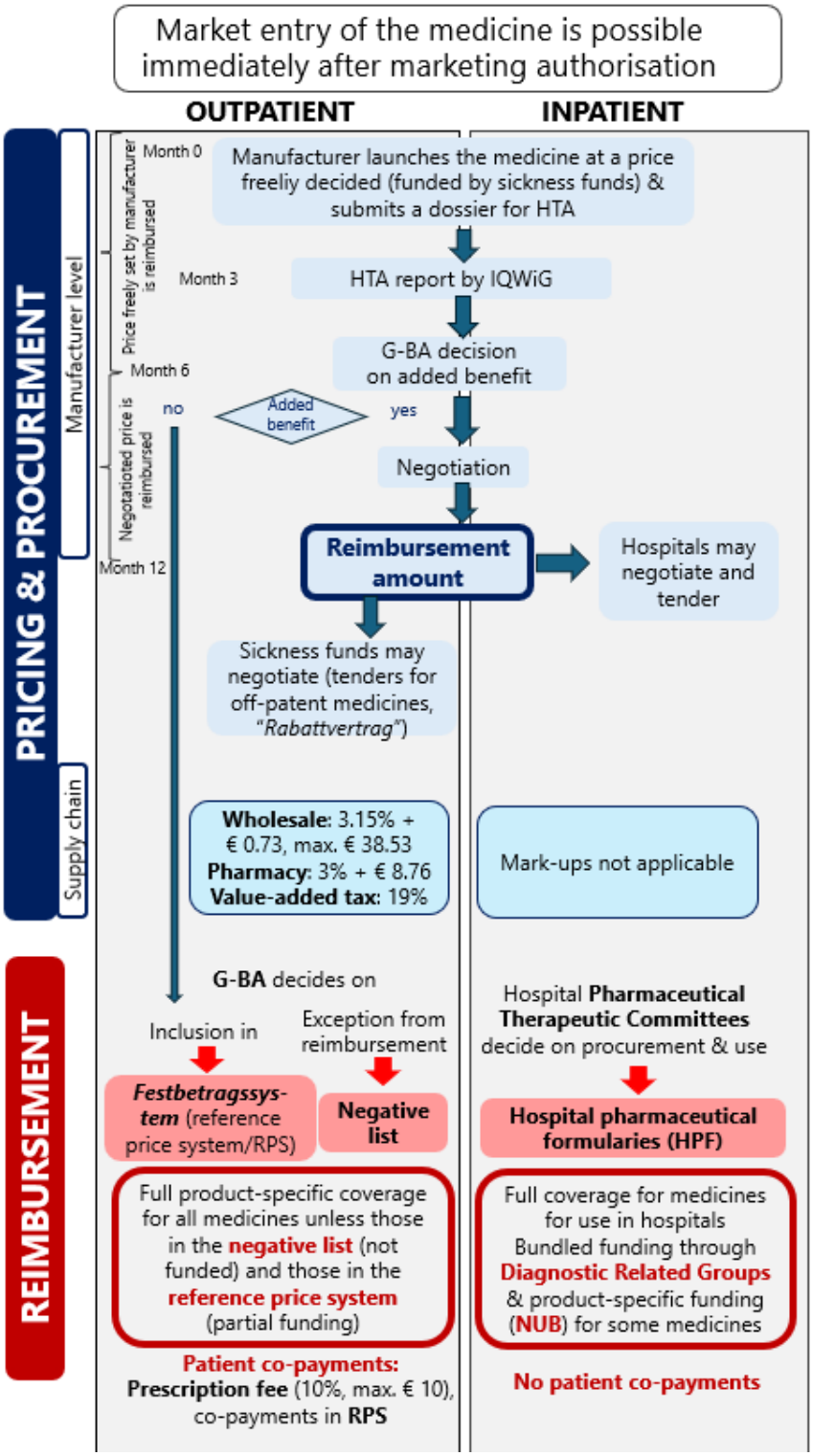
Eine **Wirkstoffverschreibung** durch Ärztinnen und Ärzte ist auf freiwilliger Basis möglich. **Generikasubstitution** in Apotheken ist verpflichtend. **Biosimilarsubstitution** wurde für ausgewählte Wirkstoffe im März 2024 eingeführt.

Seit seiner Einführung im Jahr 2011 erfuhr das **AMNOG** einige **gesetzliche Änderungen**, zuletzt die Ermöglichung vertraulicher Rabatte unter bestimmten Bedingungen seit 2025 (Medizinforschungsgesetz – MFG).

Schlagwörter

Preisbildung, Erstattung, Arzneimittelpolitik, Arzneimittelsystem, Deutschland

Graphical summary



Source: Graph by author (PPRI Secretariat)

1 Framework

The German **health system** is complex and **decentralised**: Responsibilities are divided between the federal and state levels and corporatist bodies of self-governance. Organisational and funding structures differ between the outpatient and inpatient sectors. It is a multi-payer social health system based on mandatory statutory health insurance (SHI / *Gesetzliche Krankenversicherung* / GKV), provided by 95 sickness funds [14], and substitutive private health insurance (PHI), which is offered by 41 private health insurance companies [15]. In the pharmaceutical system, different organisational and funding frameworks also apply for the outpatient and inpatient sectors.

The Medicines Law (*Arzneimittelgesetz* / AMG), which provides key definitions and classifications for medicines (e.g., with regard to the prescription status and the health providers permitted to dispense medicines), applies to human medicines only since January 2022 (before 2022 it applied to human and veterinary medicines). Further **key national legislation** relating to medicines include the *Arzneimittelpreisverordnung* (AMPreisV) to regulate pricing for pharmaceutical wholesalers and community pharmacies, the Social Code V (*Sozialgesetzbuch (*SGB) V) to determine the eligibility of insured persons to receive medicines on their social health insurance and the *Arzneimittelmarktneuordnungsgesetz* (**AMNOG**). The latter provided the legal basis for the introduction of a new pharmaceutical pricing and reimbursement scheme in 2011, which included the implementation of a Health Technology Assessment (HTA) process and price regulation for defined medicines. Over the years, additional laws to provide specifications and changes to AMNOG were adopted (see also the following chapters).

Major relevant competent **authorities** for medicines are the following:

- The Federal **Ministry of Health** (*Bundesministerium für Gesundheit* / BMG) is responsible for coordinating overall legislation in health care, including medicines.
- The **Federal Institute for Pharmaceuticals and Medical Devices** (*Bundesinstitut für Arzneimittel und Medizinprodukte* / BfArM), which is a subordinate agency to the Ministry of Health, is Germany's Medicines Agency, thus responsible for the marketing authorisation of medicines (unless those under PEI's responsibility, see below). As Germany is a European Union (EU) Member State, marketing authorisation is part of the harmonised European procedures, meaning that national regulation applies only when the medicine has not been subject to the centralised marketing authorisation procedure of the European Medicines Agency (EMA). The BfArM is also responsible for monitoring medicines (and medical devices) and for managing medicine shortages. However, the marketing authorisation of blood, blood products, sera, vaccines, advanced therapy medicinal products (ATMPs), allergens and tissues is the responsibility of the Federal Institute for Vaccines and Biomedicines (*Paul-Ehrlich-Institut* / PEI). In 2020, the German Institute for Medical Documentation and Information (*Deutsches Institut für Medizinische Dokumentation und Information* / DIMDI), which operates the German medicines databases, including a module on reimbursement and co-payment amounts, was merged into the BfArM.

- The **Institute for Quality and Efficiency in Healthcare** (*Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen* / IQWiG) is Germany's "lower HTA body", thus responsible for the assessment part.
- The **Federal Joint Committee** (*Gemeinsamer Bundesausschuss* / G-BA) is the key decision-making body within the system of joint self-governance with representatives of different stakeholders. The G-BA decides on the inclusion of medicines into the SHI, thus reimbursement, guided by HTA reports prepared by IQWiG. Thus, the G-BA is responsible for the appraisal of medicines and can be considered as the "higher HTA body".
- The **Federal Association of Sickness Funds** (*GKV-Spitzenverband*), which represents 95 sickness funds in the SHI system, negotiates the maximum reimbursement price of medicines.

Pricing and reimbursement processes are strongly interlinked in Germany, since price regulation based on AMNOG concerns the negotiated manufacturer price for medicines in the SHI, which represents the reimbursement amount paid by the sickness funds. In Germany, pharmaceutical companies may launch medicines immediately upon marketing authorisation; the marketing authorisation holder (pharmaceutical company) defines the price freely which is funded by the social health insurance until the end of the 6. months.

2 Pricing

Pricing at manufacturer price level

Before the introduction of **AMNOG in 2011, free pricing** was in place for all medicines in Germany, with the pharmaceutical company free to determine the medicine price. AMNOG introduced **price regulation at manufacturer price level for medicines with a new active ingredient that are reimbursable by the social health insurance**.

However, according to the AMNOG price regulation for the reimbursed price (reimbursement amount), the marketing authorisation holder (manufacturer) initially sets the price and launches the medicine into the German market. This free pricing period used to be **12 months**. In 2022, the free pricing period was reduced to six months, and the negotiated price is applied retrospectively from **month 7** [16, 17].

In contrast to other countries in which funded medicines are usually launched after the pricing and reimbursement processes have been completed [18], a medicine can be **marketed** in Germany **as soon as** it has received its **marketing authorisation**.

At the time of market launch, the pharmaceutical company has to submit a dossier to request a Health Technology Assessment (**HTA**). This is, in principle, mandatory for all reimbursable medicines launched into the market after 1 January 2011 (introduction of the AMNOG law). Pharmaceutical companies which expect annual sales in the SHI market of less than € 1 million may request an exemption from the AMNOG processes (triviality criterion / *Geringfügigkeitskriterium*) [16].

The HTA institute IQWiG conducts an HTA (called "*Frühe Nutzenbewertung*") within three months and submits the HTA report to the G-BA [17].

Informed by IQWiG's HTA, the **G-BA determines** whether the medicine has an **added benefit**. The added benefit is measured by patient relevant outcomes of the medicine compared to its standard therapy (so-called "appropriate comparator therapy" / *zweckmäßige Vergleichstherapie);* relevant parameters include survival data, health outcomes, decrease in the length of the illness, fewer adverse reactions and improvements in the quality of life [16]. The G-BA takes this decision on the added benefit within three months after IQWiG has submitted the HTA report. Thus, the decision will be available six months after the pharmaceutical company has submitted the dossier and marketed the medicine.

For **orphan medicines**, the law stipulates that an added therapeutic value is assumed to be established based on the marketing authorisation. This applies only to orphan medicines whose sales are expected to not exceed € 30 million within twelve months (since November 2022, before, the sales threshold was € 50 million) [19]. Since 2019, for determining the sales threshold, not only sales in the outpatient sector but also those in the inpatient sector are considered [16, 20]. Since 2021, manufacturers of **reserve antibiotics** have also been exempt from submitting a full dossier for the HTA, since the added value of reserve antibiotics is also assumed to be established [21].

If the G-BA concludes that the **medicine has no added benefit**, reimbursement can be negotiated based on the most economically appropriate comparative therapy, or the medicine can be included in the **reference price system** (so-called *Festbetragssystem*) which is a variant of internal reference pricing.

Generic and biosimilar medicines, as well as medicines launched before the implementation of AMNOG in January 2011, could be clustered into the reference price system that existed prior to the AMNOG reform. According to the legal basis of § 35 SGB V, a reference group is established to include medicines of 1) the same active ingredients (reference group type 1), 2) of comparable pharmacological-therapeutical ingredients (reference group type 2), or 3) of therapeutically comparable effect (reference group type 3). Thus, the reference groups in the German system are larger than those of the reference price systems in many other countries [18], as also more than one patent-protected medicine may be included in a reference group. As of January 2025, the German reference price system includes 440 reference groups (306 reference groups type 1 containing 227 active ingredients, 72 reference groups type 2 with 204 active ingredients and 62 reference groups type 3 with 160 combinations of active ingredients) (data provided by the GKV-Spitzenverband). The G-BA decides on establishing the reference groups, and the GKV-Spitzenverband determines the reference price, which is the reimbursement amount. Inclusion of a medicine into the reference price system has implications for patient payments (see below chapter "Demand-side measures").

If the G-BA determines an **added benefit of a medicine** or for a medicine with no added benefit that cannot be included in the reference price system, the Federal Association of Sickness Funds (*GKV-Spitzenverband*) starts price negotiations with the manufacturer. While this is called "price negotiations", the "negotiated price" (*Erstattungsbetrag*) is actually the reimbursement rate paid by the sickness funds. The negotiations are informed by the findings of the HTA; in addition, since a legal reform in November 2022 (*GKV-Finanzstabilisierungsgesetz* / GKV-FinStG [22]), the patent status of the "appropriate comparator therapy" is taken into account as an additional criterion [16]. Thus, the German pricing system can be classified as strongly guided by value-based elements.

In case that the two parties do not reach an agreement, an **arbitration board** is consulted, which takes the decision based on the HTA outcome. If a medicine demonstrates an added therapeutic benefit, additional criteria can be included. Until end of 2024, the **actual paid prices** of the medicine **in fifteen reference countries** (mainly countries in Western Europe) and other prices of the medicines of the same indication were considered, but the Medical Research Law 2024 made away with this regulation from 1 January 2025 [17, 23].

The AMNOG process has to be concluded within one year, resulting in a **negotiated price (reimbursement amount),** which is applicable in the statutory social health insurance (*Gesetzliche Krankenversicherung* / GKV) and in private social health insurance (PKV) [16].

The legal reform of November 2022 introduced some specifications: If the appropriate comparative therapy is an on-patent medicine, the negotiated price should not be higher than the price of the comparator (in case of low added benefit or non-quantifiable benefit) or must be reduced

by 10% (in case of no added value of medicine). Furthermore, it must be reduced by at least (additional) 15% for medicines launched before 1 January 2011 (25% in total for on-patent medicines) [16, 23].

Mandatory manufacturer discounts granted by the pharmaceutical companies to the sickness funds are applied and defined in law (published discounts):

- 7% for on-patent medicines not included in the reference price system (in 2023, it used to be 12%)
- 10% for off-patent medicines included in the reference price system (unless for medicines reducing the price to a certain level or priced 30% below the reference price, see also the chapter "Reimbursement")
- 16% for off-patent medicines that are not included in the reference price system.

A legal reform of 2017 (*GKV-Arzneimittelversorgungsstärkungsgesetz / AMVSG*) [24] clarified that the AMNOG process is not only applicable for medicines in the outpatient sector (which are funded by the sickness funds) but also for medicines used in hospitals. Thus, the **negotiated price serves as the maximum ex-factory price for the sickness funds and hospitals** and may not be exceeded [25]. When procuring the medicines, hospitals may negotiate lower prices, usually achieved through confidential discounts (see below the section "Agreements" in the chapter "Reimbursement").

Since August 2010, a **price freeze** (*Preismoratorium*) has been in place for all medicines (except those included in the reference price system) launched before August 2009. A law of November 2022 (*GKV-Finanzstabilisierungsgesetz* / GKV-FinStG [22]) prolonged the price freeze until the end of December 2026. In cases of price increases by manufacturers, a discount of the same extent would need to be granted to the sickness funds. However, since 1 July 2018, prices may be increased to align for the official inflation rate [26].

Procurement

Procurement is used in the **outpatient** sector (for off-patent medicines) as well as in the inpatient sector. Overall, Germany's public procurement system is highly decentralised, and contracting authorities are active at federal, regional and municipal levels. Germany has four centralised purchasing bodies (CPBs) and CPBs at regional levels; however, they seldom procure medicines. At federal level, the Ministry of Health supported by its agencies PEI and BfArM (see chapter "Framework") were involved in the procurement of vaccines (including COVID-19 vaccines) and certain therapeutics for COVID-19 and monkeypox [27].

In the **inpatient** sector, procurement is conducted in a decentralised manner by hospitals; several hospitals have joined group procurement organisations such as AGKAMED or GDEKK. Hospital pharmacists play a major role in hospital procurement, where procurement decisions are taken in alignment with the hospital pharmaceutical formulary (HPF).

In the **outpatient** sector, tendering is in place (for generics, when the system started in 2007, and meanwhile also for biosimilars). Individual sickness funds launch a tender for an active ingredient, and the successful bidding company is granted a "**discount contract**" (so-called "*Rabattvertrag*"). Part of this contract is a negotiated price which is held confidential between the manufacturer and the sickness fund. In the community pharmacy, the medicines which won the tenders need to be supplied to the insured of the respective sickness funds. Since each sickness fund launches its own tenders, a community pharmacy is obliged to supply different medicines of the same active ingredients to the insured of different sickness funds [28-30].

In case of non-availability of a medicine under a "discount contract" in the community pharmacy, generic substitution to a higher-priced medicine with the same active ingredient is possible, with the price difference being paid by the sickness funds. This was introduced as part of a reform regarding the mitigation of shortages.

Some sickness funds apply **less competitive procurement methods, e.g., "Open House" contracts**. Under this variant, a sickness fund offers a contract to all competing manufacturers of an active substance in which the requested discount rate / price has been prespecified. Any manufacturer of that active ingredient willing to grant the requested discount rate / price can join the contract, without conducting any individual negotiations. For instance, the BARMER GEK sickness fund applies Open House contracts for medicines to treat Morbus Crohn and Colitis ulcerosa, combined with **prescribing quotas** for doctors on defined medicines, which request doctors to prescribe defined shares of generics and biosimilars, and so-called "selective contracts" ("*Selektivverträge*") concluded between a sickness fund and a patient. "Selective contracts" relate to integrated care models, and patients under such a "selective contract" commit for the period of the contract to a defined prescriber (who, in return, is committed to prescribe biosimilars) [31, 32].

Pricing in the supply chain

For medicines in the outpatient sector, which are included in the statutory social health insurance (reimbursable medicines) prices at wholesale and pharmacy price levels are regulated through mark-up schemes. Such price regulation does not apply for the hospital sector.

The relevant legislation is the Pharmaceutical Price Ordinance (*Arzneimittelpreisverordnung* (AM-PreisV) [33].

For prescription-only medicines funded by social health insurance, pharmaceutical **wholesalers** are allowed a maximum mark-up of 3.15% on the ex-factory prices, which is capped at € 37.80 for medicines with an ex-factory price of € 1,200, plus a fixed amount of € 0.73 per pack (thus resulting in maximum € 38.53 wholesale mark-up per medicine). Similarly, for prescription-only medicines funded by the social health insurance, **pharmacies** are paid a flat-fee of € 8.76 per pack and a fixed mark-up of 3% on the wholesale price. In case of a generic substitution attributable to a shortage, the pharmacy is granted an additional € 0.50 [33]. These mark-ups were increased in 2023 as part of a legislation to mitigate medicine shortages (see chapter "Developments").

For selective non-prescription medicines funded in special cases by the social insurance (see chapter "Reimbursement"), wholesale and pharmacy mark-ups are regulated through regressive schemes.

No price regulation is applied for medicines not covered by the social health insurance.

Sickness funds receive a mandatory pharmacy discount from community pharmacies if they pay the pharmacy within ten days upon receipt of the invoice. From 1 February 2023 until 31 January 2025 the **mandatory pharmacy discount** amounted to € 2.- per medicine [22]. Before it had been € 1.77 and it is the current discount valid again from 1 February 2025 [34].

Germany applies a **value-added tax** (VAT) of 19% on all medicines, which corresponds to the standard VAT rate.

3 Reimbursement

Reimbursement for outpatient medicines

In principle, all medicines, apart from a few defined exceptions, are reimbursable and covered by mandatory social health insurance (statutory or private health insurances). Germany does not have a positive list of medicines.

Exceptions, which constitute the **negative list**, include the following:

- non-prescription medicines except for children under the age of 12 or for adults for specific indications when considered as standard therapy in the treatment of serious diseases (e.g., acetylsalicylic acid as an antiplatelet aggregation inhibitor in coronary heart disease) as defined by the Federal Joint Committee (G-BA)
- medicines for "trivial" diseases (common colds, oral cavity medicines except for antifungals, laxatives and medicines for motion sickness) for insured adults over 18 years
- so-called lifestyle medicines (e.g., for the treatment of erectile dysfunction, overweight), even if they are prescription-only.

The G-BA defines these exceptions and develops the negative list.

Overall, the G-BA plays a major role in the AMNOG system, since it acts as an appraisal body ("higher HTA body") and determines whether a medicine has an additional benefit. The G-BA also establishes the reference groups in the reference price system (*Festbetragssystem*), see chapter "Pricing".

The Federal Association of Sickness Funds (*GKV-Spitzenverband*) is the reimbursement authority which negotiates with the manufacturers (price negotiations in case of medicines with a benefit assessment), and it also sets the reimbursement amount per reference group in the reference price system.

Main payers of the statutory health insurance (SHI) and private health insurance (PHI) are the single sickness funds (in the SHI) and private health insurers (in the PHI). Prescribed medicines are, in principle, **covered 100%**, but patients are charged a co-payment for filling a prescription in a community pharmacy. There are different types of prescriptions: red prescriptions (for patients in the SHI, valid for one month), blue "private prescriptions" (for patients in the PHI or SHI insured for a prescription-only medicine which is not included in the benefits basket scheme, validity of three months), yellow prescriptions (for strong-acting substances whose prescription is subject to narcotics legislation, e.g., certain painkillers such opioids, validity of 7 days) and green prescriptions (for non-prescription medicines recommended by a doctor, to be paid by the patient, no limitation in validity) [35].

People insured in the German SHI system are charged a co-payment of 10% of the price of an on-patent medicine, however, € 5.- as a minimum und € 10.- as a maximum (**prescription fee**). Children and young people under the age of 18 years are exempt from co-payments. For people with

chronic diseases co-payments are capped at 1% of the annual gross income and for all others insured, the cap is set at 2% of the annual gross income.

Further patient payments may be charged if the insured person requests a medicine included in the reference price system that is priced above the reference price. However, the GKV-Spitzenverband may exempt a medicine with a pharmacy retail price which is 20 percent below the reference price (it used to be 30% but the amount was reduced to decrease price competition as a measure to mitigate medicine shortages, see also chapter "Developments"). In cases of medicines tendered by sickness funds which have not been exempted by the GKV-Spitzenverband, the sickness funds are allowed to reduce the co-payments and not charge any co-payments, and this practice was indeed applied by sickness funds [36].

Insured people in private social insurance pay the full price out-of-pocket but may request their private health insurance to reimburse up to the reimbursement amount.

Reimbursement for inpatient medicines

Medicines used in hospitals are mainly funded through the bundled Diagnosis Related Group (**DRG**) system, which is complemented by the "New Diagnostic and Treatment Methods" system (*Neue Untersuchungs- und Behandlungsmethoden* / **NUB**). The NUB system allows receiving product-specific funding for medicines which have not yet been included in the DRG system. The rationale of the NUB system, which came into effect in 2005, is to address a potential time lag (up to three years) until a medicine is included in the DRG or an additional remuneration (ZE – *Zusatzentgelt)* is installed. To bridge this period, hospitals can apply for separate NUB funding (NUB tariffs) on an annual basis, which will be valid for one year and only applicable to the individual hospital. NUB applications are assessed by the Institute for the Hospital Remuneration System (*Institut für das Entgeltsystem im Krankenhaus* / InEK), and in case of a positive assessment, the reimbursement tariffs will be negotiated by the sickness funds and health insurers with the hospital [37].

In the hospital sector, positive lists are available in the form of **hospital pharmaceutical formularies** (HPF), which have been established and are managed by each hospital. Each hospital has a Pharmaceutical Therapeutic Committee (PTC), which decides on the inclusion of medicines in the hospital pharmaceutical formularies [27]. For high-priced medicines, hospitals may conclude managed-entry agreements with a confidential discount (see below "Agreements").

As described in chapter "Pricing", the 2017 AMVSG law provided clarifications of the scope of the AMNOG process (i.e. the negotiated price to serve as maximum benchmark also for hospitals). Based on this law, the G-BA decided in January 2018 that an **HTA** will also be conducted for medicines exclusively used in hospitals [25].

No co-payments are charged for medicines used in the hospital sector [38].

Agreements

Previously, no managed-entry agreements were concluded at central level as part of the AMNOG process, and the reimbursement amounts were public. The Medical Research Law valid from January 2025 gives manufacturers who provide evidence that they conduct pharmaceutical research in Germany the possibility to negotiate a confidential reimbursement amount. In return for the confidential agreements, manufacturers have to grant a mandatory discount of 9% [39, 40].

Over the decade, in their procurement processes, hospitals have been concluding agreements with manufacturers, which contained confidential discounts. Further details on these agreements in hospitals, which would correspond to what is labelled managed-entry agreements (MEAs) in other countries, are not available [27].

Sickness funds have been concluding "discount agreements" (*Rabattverträge*), which comprise confidential discounts and prices. Since these are tendering procedures for off-patent medicines (see section "Procurement" in chapter "Pricing"), they are not labelled MEAs.

Demand-side measures

As described above in the section "Pricing at manufacturer price level", Germany has a reference price system (so-called *Festbetragssystem*) that includes medicines which have no proven added benefit. If a patient insists on being dispensed a medicine with a pharmacy retail price above the reference price, then s/he has to pay the difference between the reference price and the pharmacy retail price (co-payment called "*Aufzahlung*"), in addition to the standard co-payment in the form of a prescription fee described above (so-called "*Zuzahlung*"). However, if the pharmacy price of a medicine is 20% below the reference price (before: 30%, see also chapter "Developments"), the GKV-Spitzenverband can exempt the medicine from the standard co-payment (*Zuzahlung*). As of January 2023, 10.3% of all medicines included in the reference price system were exempt from that co-payment [41].

Prescribing by International Non-Proprietary Name (**INN**) is allowed on a voluntary basis. However, in the case of biologicals the pharmacist has to consult with the prescribing doctor.

Generic substitution (aut-idem) is obligatory.

Biosimilar substitution is in place for selected medicines. The legal basis (*Gesetz für mehr Sicherheit in der Arzneimittelversorgung* / GSAV) [42] was passed in 2019 and originally provided for the implementation of biosimilar substitution in community pharmacies in summer 2022 under the condition that the G-BA will have decided on the substitutability of the medicines and the prescribing doctor has not excluded the substitution. Implementation of the law was postponed by one year. In March 2024, biosimilar substitution was introduced and applies to the active substances of bevacizumab, eculizumab, infliximab, rituximab, tocilizumab and trastuzumab [43].

4 Developments

Since its introduction, the **AMNOG process has been amended** in some details, through **additional laws**. Between January 2011 and end of 2020, the respective Social Law (*Sozialgesetzbuch* / SGB V) was changed eleven times (amendments and new laws) which corresponds to changes on an annual basis [23]. In addition, following a reform of November 2022, the negotiated price (reimbursement amount, which used to become effective in month 13), is valid retrospectively from month 7 [16, 22]. That law also extended a price freeze (*Preismoratorium*) until December 2026 [26].

Over the years, Germany has also seen changes regarding the extent of the mandatory manufacturer and pharmacy **discounts** (see chapter "Pricing").

In response to an increasing number of **medicine shortages**, the German government passed a comprehensive law (*Arzneimittel-Lieferengpassbekämpfungs- und Versorgungsverbesserungsgesetz* / ALBVVG) in July 2023, which contained several measures for improved management and mitigation of medicine shortages: The Medicines Agency was tasked to establish an early warning system for upcoming medicine shortages and to draw a list of "critical shortages" (i.e. relating to active substances that are relevant or critical for supply). Stocking obligations of six months for outpatient off-patent medicines under a rebate contract were introduced. It is planned to prioritise bids of suppliers with production of active pharmaceutical ingredients in Europe in public procurement, starting with considering the award criterion of local production for antibiotics in the short run. The law also provided for financial incentives: some medicines for children were exempted from being included into the "*Festbetragssystem*". Patients will not be charged higher co-payments if co-payment increases were attributable to a shortage-related substitution of the prescribed medicine. A change in the co-payment regulation (possibility to exempt medicines from co-payment in case of a price 20% below the reimbursement amount, compared to 30% in 2023) to reduce price competition was another element in the law on measures to mitigate shortages [44].

In December 2023, the Federal Government introduced a Pharmaceutical Strategy with a view to improve attractiveness of the German market for pharmaceutical research and production. [45, 46]. In 2024, the Medical Research Law was passed, entering into force from January 2025 [39]. It implemented measures proposed in the Strategy, such as facilitation and acceleration of clinical trials and the possibility for manufacturers to negotiate confidential reimbursement amounts. This is a temporary measure until June 2028 [47].

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6 Annex

Annex 1: Stakeholders

Role	Name in local language	Website(s)
Competent authority for marketing authorisation of medicines	Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) Paul-Ehrlich-Institut (PEI)	www.bfarm.de/DE/Home/_node.html www.pei.de/DE/home/home-node.html
Competent authority for legislation of medicines	Bundesministerium für Gesundheit (BMG)	www.bundesgesundheitsministerium.de
(Lower) Health Technology Assessment (HTA) institute	Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG	www.iqwig.de
(Higher) Health Technology Assessment (HTA) authority	Gemeinsamer Bundesausschuss (G-BA)	www.g-ba.de
Competent authority for pricing and reimbursement of medicines (outpatient)	GKV-Spitzenverband	www.gkv-spitzenverband.de
Public payer(s) for outpatient medicines	Sickness funds in the statutory social health insurance (Gesetzliche Krankenversicherung / GKV) and the private social health insurance	Largest sickness funds in GKV: Techniker Krankenkasse (TK) www.tk.de/techniker, BARMER htt-www.barmer.de, DAK Gesundheit www.dak.de , AOK Bayern www.aok.de/pk/bayern
Public payers for inpatient medicines	*Same as for the outpatient sectors*	See above
Medicine procurement agencies	*No procurement agency specialized on medicines*	-
Patient organisations	BundesArbeitsGemeinschaft der PatientInnenstellen (BAGP) Deutsche Arbeitsgemeinschaft Selbsthilfegruppen e.V. (DAG-SHG) Deutscher Behindertenrat (DBR)	www.bagp.de www.dag-shg.de www.deutscher-behindertenrat.de
Consumer organisations	Verbraucherzentrale Bundesverband e. V.	www.vzbv.de
Pharmacy associations	ABDA - Bundesvereinigung Deutscher Apothekerverbände e. V. ADKA - Bundesverband Deutscher Krankenhausapotheker e.V. (hospital pharmacists)	www.abda.de www.adka.de
Industry associations	Pharma Deutschland (called Bundesverband der Arzneimittel-Hersteller (BAH) until 3/2024) Verband der forschenden Arzneimittelhersteller (VfA) Bundesverband der pharmazeutischen Industrie (BPI): (small and middle-sized companies) Pro Generika (generic companies)	www.pharmadeutschland.de www.vfa.de www.bpi.de www.progenerika.de
Wholesale association	Bundesverband des Pharmazeutischen Großhandels (PHAGRO e. V.)	www.phagro.de

Source: mapping done for this PPRI Pharma Brief

Annex 2: Glossary

Claw-back	A policy where funds already paid by public payers to pharmaceutical companies, wholesalers or pharmacists have to be paid back to the third party payers under certain conditions (e.g. if a certain threshold is exceeded).
Community pharmacy	Health care facilities dispensing medicines (prescription-only medicines and/or OTC medicines, reimbursable and non-reimbursable medicines) to outpatients.
Co-payment	Patient's contribution towards the cost of a medicine or health service covered by a third party payer (e.g., a public payer). Common types of co-payments for medicines include a percentage of the total expense of the medicine or service (percentage co-payment), as a fixed amount (prescription fee) and a deductible.
Cost-plus pricing	Pricing policy that takes into account production costs, promotional expenses, research & development, administration costs, overheads and a profit to determine a price.
Discount	A price reduction granted to specified purchasers under specific conditions prior to purchase.
Dispensing fee	Normally a fixed fee that pharmacies are allowed to charge per prescribed item instead of or in addition to a percentage mark-up. The fee more accurately reflects the work involved in dispensing a prescription; a percentage mark-up makes profit dependent on the sale of expensive medicines.
External price referencing	The practice of using the price(s) of a medicine in one or several countries in order to derive a benchmark or reference price for the purposes of setting or negotiating the price of the product in a given country.
Free pricing	Pricing policy, in which governments allow pharmaceutical companies to determine the price of the medicine they launch.
Generic substitution	The practice of dispensing a medicine, whether marketed under a trade name or generic name (branded or unbranded generic), with a less expensive medicine (e.g. branded or unbranded generic), often containing the same active ingredient(s); usually at pharmacy level without consulting the prescriber (automatic substitution).
Health Technology Assessment (HTA)	HTA is a multidisciplinary process that uses explicit methods to determine the value of a health technology at different points in its lifecycle. The purpose is to inform decision-making in order to promote an equitable, efficient, and high-quality health system.
International non-proprietary name (INN) prescribing	Requirements for prescribers (e.g. physicians) to prescribe a medicine by its INN, i.e. the active ingredient name instead of the brand name. INN prescribing may be allowed (indicative INN prescribing) or required (mandatory/obligatory INN prescribing).
Managed-entry agreement (MEA)	An arrangement between a manufacturer and payer/provider that enables access to (coverage/reimbursement of) a health technology subject to specified conditions. These arrangements can use a variety of mechanisms and are usually classified into financial-based and performance-based MEA. The latter links price (reward for manufacturers) to health outcomes.
Marketing authorisation	A licence issued by a medicines agency approving a medicine for market use based on a determination by authorities that the medicine meets the requirements of quality, safety and efficacy for human use in therapeutic treatment.
Mark-up	Percentage of the purchasing price added on to get the selling price. A mark-up is added on to the total cost incurred by the producer of a good in order to create a profit.

Pharmaceutical expenditure	Total expenditure on pharmaceutical and other medical nondurables. This comprises medicinal preparations, branded and generic medicines, on-patent medicines, serums and vaccines, vitamins and minerals and oral contraceptives. Other medical nondurables include a wide range of medical nondurables such as bandages, elastic stockings, incontinence articles, condoms and other mechanical contraceptive devices. Pharmaceutical expenditure can be separated into: • public expenditure: pharmaceutical expenditure incurred by public funds (state, regional and local government bodies and social security schemes) and • private expenditure: privately funded part of total pharmaceutical expenditure – private sources of funds include out-of pocket payments (both over-the-counter and cost-sharing), private insurance programmes, charities and occupational health care.
Policies (policy measures)	Instruments, tools and approaches that allow policy-makers to achieve defined objectives. Examples for pharmaceutical policy measures are price cuts or changes in the methodology of distribution remuneration (in the field of pricing), changes in co-payments or in the methodology of reference price systems (in the field of reimbursement), and pharmaceutical budgets and generic substitution.
Price link policy	Practice of setting the price of a medicine (e.g. a generic or a biosimilar) in relationship to the price of another medicine (e.g. originator, biological reference medicine), usually at a certain percentage lower.
Pricing (price setting)	Action by a government authority to set the price of a medicine and/or indirectly influence it (e.g. through pricing policies) for different price types (e.g. ex-factory price, pharmacy retail price) and to monitor and review and eventually adapt it.
Price negotiation	A pricing procedure in which medicine prices are discussed and agreed by seller and purchaser (e.g. between manufacturer and third party payer).
Price regulation (price control)	Pricing policies where government authorities set the price of a medicine and/or indirectly influence it (e.g. statutory pricing, price negotiations, public procurement).
Procurement	A process to purchase goods and services (e.g. medicines) that involves many steps and many stakeholders based on national, or supranational, regulation, policies, structures and procedures.
Reference price system	A reimbursement policy in which identical medicines (ATC 5 level) or therapeutically similar medicines (ATC 4 level) are clustered (reference group). The third party payer funds a maximum amount (= reference price), while the patient must pay the difference between the reference price and the actual pharmacy retail price of the medicine, in addition to any co-payments.
Reimbursable medicines	Medicines which are eligible for reimbursement. Expenses of reimbursable medicines may be fully covered by third party payers, or only partially (a specific percentage).
Reimbursement	Coverage of the expenditure by a third party payer (e.g. social health insurance/National Health Service).
Reimbursement list	A list that contains medicines with regard to their reimbursement status. It may either include medicines eligible for reimbursement (positive list) or those explicitly excluded from reimbursement (negative list).
Tendering	Any formal and competitive procurement procedure through which tenders (offers) are requested, received and evaluated for the procurement of goods, works or services, and as a consequence of which an award is made to the tenderer whose tender/offer is the most advantageous.
Value-based pricing	Policy of authorities to set the prices of a new medicine and/or decide on reimbursement based on the therapeutic value that a medicine offers, usually assessed through health technology assessment (HTA) or economic evaluation. In a full-fledged VBP, the pricing and reimbursement systems are integrated, and the price and reimbursement decision is taken jointly based on a value assessment.
Wholesale	All activities consisting of procuring, holding, supplying or exporting medicines, apart from supplying medicines to the public.

Source: Knoll & Vogler. PPRI Glossary of Pharmaceutical Terms. Update 2025 [48]