Reimbursement of Pharmaceuticals in Germany

2018

Finding Your Way into the German Pharmaceutical Market

The German Market and Access to it
03–09

04 Germany – Europe's Most Important Destination for Pharmaceuticals

06 The European Regulatory System for Pharmaceuticals

08 Understanding the German Health Care System

General Concept of Reimbursement in Germany
10–23

11 Outpatient

22 Inpatient

IGES Group
24

Glossary
25

IGES Institute was founded in 1980 and has become one of Germany's most important voices for the health care sector. It is independent, and fully owned and operated by its scientists. We offer creative solutions for questions in care, quality, financing and shaping competition for all actors in the life sciences arena. Our clients are government organizations, NGOs and companies. We have broad access to data sources – both our own and those of other institutions. We approach all issues brought to us on the basis of data and facts, which we analyze with the best available methods. The institute has conducted over 2,000 research and consulting projects for various clients since its conception.

Our Comprehensive Services:

- Value demonstration of pharmaceuticals for reimbursement
- Dossiers for early benefit assessment and clinical evaluation of drugs
- Health technology assessment (HTA)
- Real-world and care provision analyses
- Clinical trials: planning, consultation and evaluation
- Assessment of inpatient and ambulatory sector potentials
- Competition and regulation analysis
- Pricing and market access
- Portrayal of individual product reimbursement pathways
- Assistance with review processes conducted by the Federal Joint Committee (G-BA)

ⓘ About this Guide

Our partners in Germany and abroad asked us for an overview of the German reimbursement system. With this guide, we explain the basic principles of the German regulatory framework for pharmaceuticals for human use with a particular focus on reimbursement. It has been written with utmost care. However, no document can replace a face-to-face meeting and qualified consultancy.

The German Market and Access to it

Germany – Europe's Most Important Destination for Pharmaceuticals

Market Access

Germany has several advantages for pharmaceutical companies, such as its market size, reliable legal framework for approval and reimbursement, as well as the quality and cost-effectiveness of its clinical research.

In 2015, the global pharmaceutical market was 1.07 trillion USD. The US has the largest market with 433 billion USD, second is China with 115 billion USD, third is Japan with 81 billion USD, and Germany has the world's fourth largest market with 43 billion USD. The German market is Europe's largest market.

Germany ranks fourth in the world as a location for conducting clinical trials. It has a global market share of 6.7% for all clinical studies, following the US (44%), China (9.8%) and Canada (7.2%).

The Largest European Pharmaceutical Markets in 2016

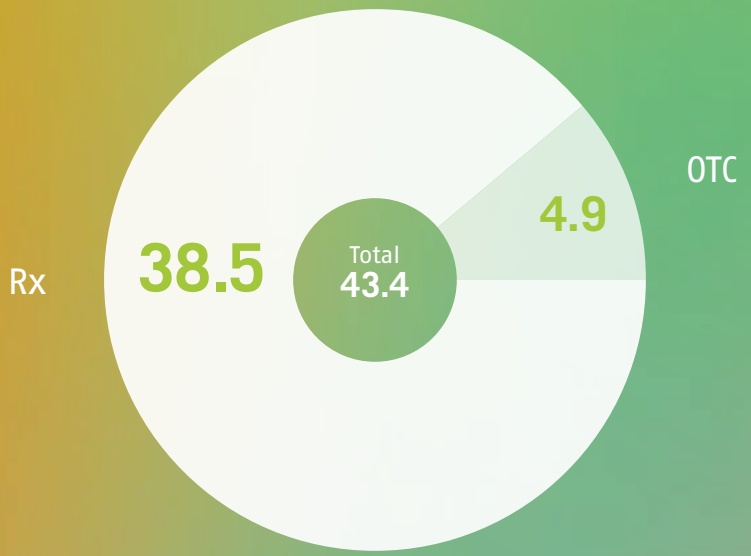
EU Member State	Turnover in billion	
	USD	Euro
Germany	$44.20	€40.98
France	$33.11	€30.69
Italy	$29.03	€26.91
UK	$26.41	€24.48
Spain	$21.13	€19.59

Manufacturer turnovers (ex-factory-price)

Source: IGES based on BPI e. V. (Federal Association of the Pharmaceutical Industry), Pharmadaten 2017, p. 40

The German Pharmacy Market in 2016

Total turnover of pharmaceuticals in German pharmacies:
43.4 billion euros (retail price (pharmacy price) excluding VAT)



See page 15 for more details about the price structure.

Source: IGES based on ABDA (Federal Union of German Associations of Pharmacists), Die Apotheke – Zahlen, Daten, Fakten 2017, p. 58

The European Regulatory System for Pharmaceuticals

The European system provides different routes for authorizing medicines.

Decentralized Procedure

The majority of medicines are authorized by national competent authorities (NCAs) in the member states. There are two NCAs for human drugs in Germany:
The Bundesinstitut für Arzneimittel und Medizinprodukte – BfArM (Federal Institute for Drugs and Medical Devices) and the Paul-Ehrlich-Institut. BfArM is responsible for licensing all human medicinal products, except sera, vaccines, allergens and blood products which are licensed by the Paul-Ehrlich-Institut.

Companies can use one of the following procedures to authorize a drug in several member states:

Decentralized procedure
Companies can apply for simultaneous authorization of a medicine in more than one EU member state provided the drug has not yet been authorized in an EU country and does not fall into the mandatory scope of the centralized procedure (see p. 7).

Mutual-recognition procedure
Companies that have a medicine authorized in one EU member state can apply for recognition of this authorization in other EU countries. This process allows member states to rely on each other's scientific assessments. Regulations and requirements for pharmaceuticals are identical throughout the EU, irrespective of the authorization route.

SME-Office

The EMA grants specific incentives to companies with a turnover of less than 50 million euros and with fewer than 250 employees.

The incentives include:

- Regulatory and administrative assistance from the SME Office
- Fee incentives (up to 100 per cent reduction)
- Assistance with the product information translations required for EU marketing authorization

Centralized Procedure

Under the centralized procedure, pharmaceutical companies submit a single marketing authorization application to the European Medicines Agency (EMA). The centralized procedure is compulsory for certain medicines and is used for most innovative medicines. The EMA's Committee for Medicinal Products for Human Use (CHMP) conducts a scientific assessment of the application and makes a recommendation on whether or not a marketing authorization should be granted. Once granted by the European Commission, the centralized marketing authorization is valid in the European Economic Area (all 28 EU member states plus Liechtenstein, Iceland and Norway). This single marketing authorization permits the marketing-authorization holder to market the medicinal product and make it available throughout the EU.

Orphan Drugs

The EU legislation provides incentives for sponsors/pharmaceutical companies to develop orphan drugs. To qualify for these incentives, products must meet the EMA orphan designation procedure's criteria.

Incentives:

- Market exclusivity: Orphan medicinal products benefit from market exclusivity in the EU for 10 years after marketing authorization has been granted,
- Protocol assistance: EMA provides scientific advice for applicants to help maximize the chances of success for their marketing authorization application
- Fee reductions
- Grants: EU-funded research sponsors may be eligible for EU and member state programs

Understanding the German Health Care System

Germany has approximately 80.2 million inhabitants. 71.4 million citizens are covered by the GKV (Gesetzliche Krankenversicherung = statutory health insurance), around 8.8 million are covered by the PKV (Private Krankenversicherung = private health insurance) including citizens are insured via state aid. GKV is provided by around 100 statutory health insurance funds. These GKV funds provide comprehensive health care. The GKV is a compulsory insurance system which may only be left in favor of the PKV if certain requirements (annual income, liberal profession, etc.) are met. Health insurance is mandatory for German citizens.

5 Largest Statutory Health Insurance Funds by Members:

Techniker Krankenkasse, TK	9 930 800
Barmer GEK	9 351 700
DAK-Gesundheit	5 847 500
AOK Bayern	4 467 200
AOK Baden-Württemberg	4 228 700

Source: IGES , data for 2017

Private and Statutory Health Insurances by Members

(in millions)

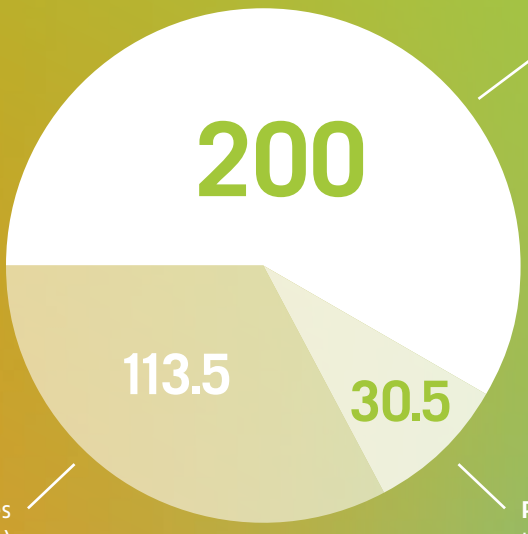
Private health insurance members (Private Krankenversicherung (PKV)) and citizens insured via state aid

Statutory health insurance members (Gesetzliche Krankenversicherung (GKV))

Source: IGES based on GKV-S, Kennzahlen der gesetzlichen Krankenversicherung and own calclulation, data for 2017

Healthcare Expenditure

Total annual healthcare expenditure in Germany is 344 billion euros, of which 200 billion euros are spent by the statutory health insurance funds. Private health insurance companies spend 30.5 billion euros.



Statutory health insurance healthcare expenditure in billion euros

Other healthcare expenditures (out-of-pocket, government, etc.) in billion euros

Private health insurance healthcare expenditure in billion euros

Total healthcare expenditure in Germany is **344 billion euros**

Source: German Federal Statistical Office, data for 2015.

General Concept of Reimbursement of Pharmaceuticals in Germany

A crucial factor for the reimbursement of a medicinal product is whether it will be used in a hospital (inpatient) or ambulatory (outpatient) setting. The following pages explain the reimbursement system for patients in the GKV (i.e. statutory health insurance).

Outpatient

Reimbursement of Pharmaceuticals in Primary (Ambulatory) Care

There are different pharmaceutical reimbursement pathways that must be used in outpatient care. These are explained on the following pages. However, competition and market environment play a crucial role in identifying the ideal solution for establishing a new pharmaceutical product in ambulatory care. Both aspects – regulatory pathways and market situation – have to be considered carefully.

Scope of GKV Benefits and Patient Co-payments

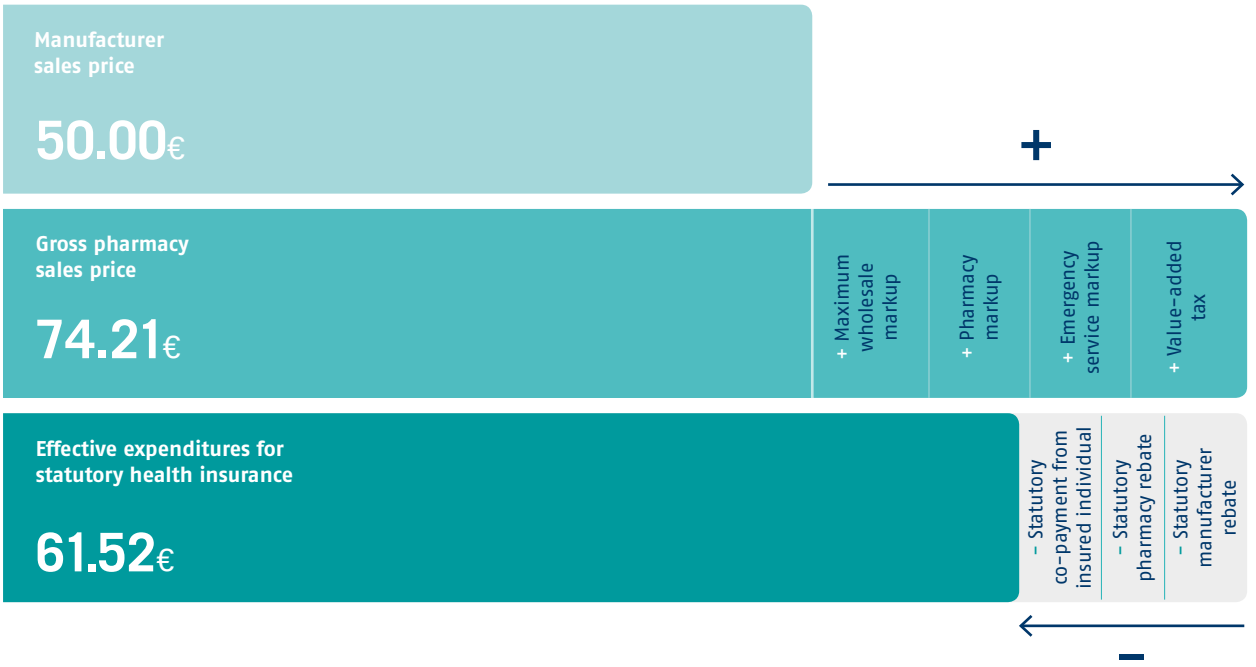
As a general rule, the GKV covers prescription-only drugs. Certain pharmaceuticals, such as life-style drugs (for instance for the treatment of hair loss) are exempt from coverage. Furthermore, the Ministry of Health has drawn up a list of pharmaceuticals which are considered "unnecessary" for reaching 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 18 and for the treatment of some chronic conditions in adults.

Patients have obligatory out-of-pocket payments ranging between 5 and 10 euros for each prescription. Drugs which are priced 30% below the reference price (see below) may be excluded from out-of-the pocket 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.

Final Price of a Prescription-only Medicinal Product (Example)



Source: IGES based on ABDA (Federal Union of German Associations of Pharmacists), Zahlen, Daten,Fakten 2016, p. 26

Ex-factory Price

Once a pharmaceutical product has been authorized, it is immediately eligible for reimbursement from the GKV funds. The initial price for a product can be freely set by the manufacturer for a period of 12 months after market launch. This initial price must be officially declared and subsequently applies to all sales of the product in Germany. After the 12 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 Discounts

A patient with a prescription for a particular drug obtains it in the 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 discounts are deducted from the pharmacist's reimbursement claim against a GKV fund. This rule does not apply to pharmaceuticals grouped in reference price groups (see below). The pharmacist can claim back the manufacturers' discount for patent protected pharmaceuticals and the generics discount for generics from the pharmaceutical manufacturers. The pharmacists' discount has to be borne by the pharmacists.

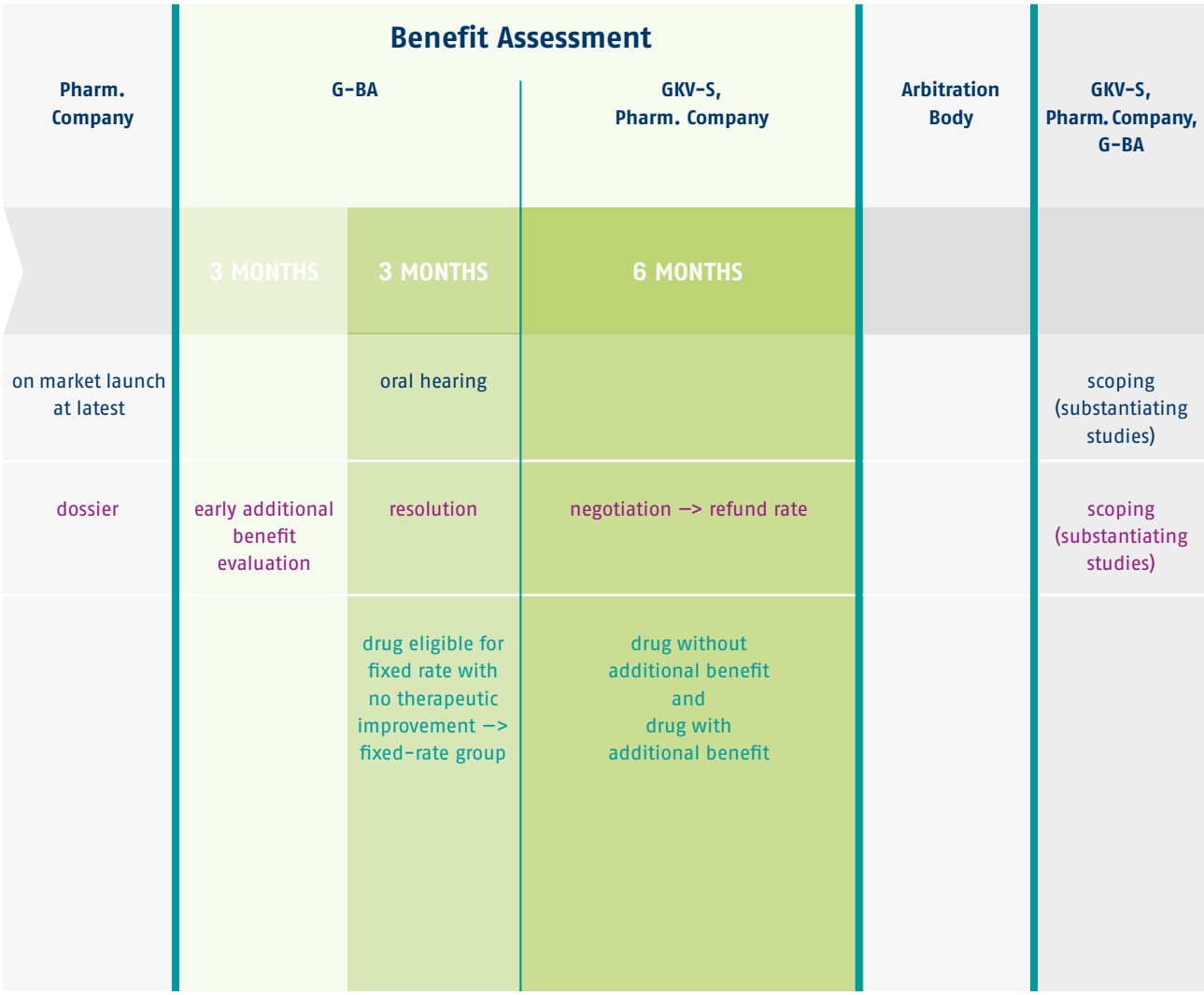
Benefit Assessment for New Pharmaceuticals

As described above, the pharmaceutical manufacturer is allowed to initially set the ex-factory price for the pharmaceutical product for a period of 12 months after 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 with 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 based on the authorization documents and on all studies carried out on this product. The additional benefit is assessed by the G-BA. The price of an innovative pharmaceutical product is based on its additional benefit: it is evaluated in the light of the therapy for which it is intended and must demonstrate an additional benefit over the comparative therapies specified by the G-BA. The G-BA can delegate the benefit assessment to the Institute for Quality and Efficiency in Health Care (IQWiG) or third parties.

Benefit Assessment Evaluation of New Pharmaceuticals Timeframe

Benefit assessment for new pharmaceuticals is a step-by-step procedure between the pharmaceutical company, GKV-S and G-BA.



Source: IGES based on GKV-S

Price Negotiation

If an additional benefit has been determined, the GKV-S initiates negotiations with the pharmaceutical manufacturer about a surcharge on the price of the equivalent comparable therapy. If it is not possible to prove any additional benefit in comparison to the expedient comparative therapy, the product is allocated to a reference price group with comparable active ingredients. If no such reference price group exists, the GKV-S negotiates a refund rate with the manufacturer, which does not lead to higher annual therapy costs than the equivalent comparable therapy.

Reference Pricing

Reference prices are upper limits for reimbursement which have been determined by the G-BA and the GKV-S for groups of similar or therapeutically comparable active ingredients. Reference price groups cover most generic drugs in Germany and also patented pharmaceuticals if three or more therapeutic alternatives to the active ingredient exist. Patented pharmaceuticals are often benchmarked against generics, particularly when the patented active ingredient belongs to a class of drugs with alternative ingredients which are already available as generics.

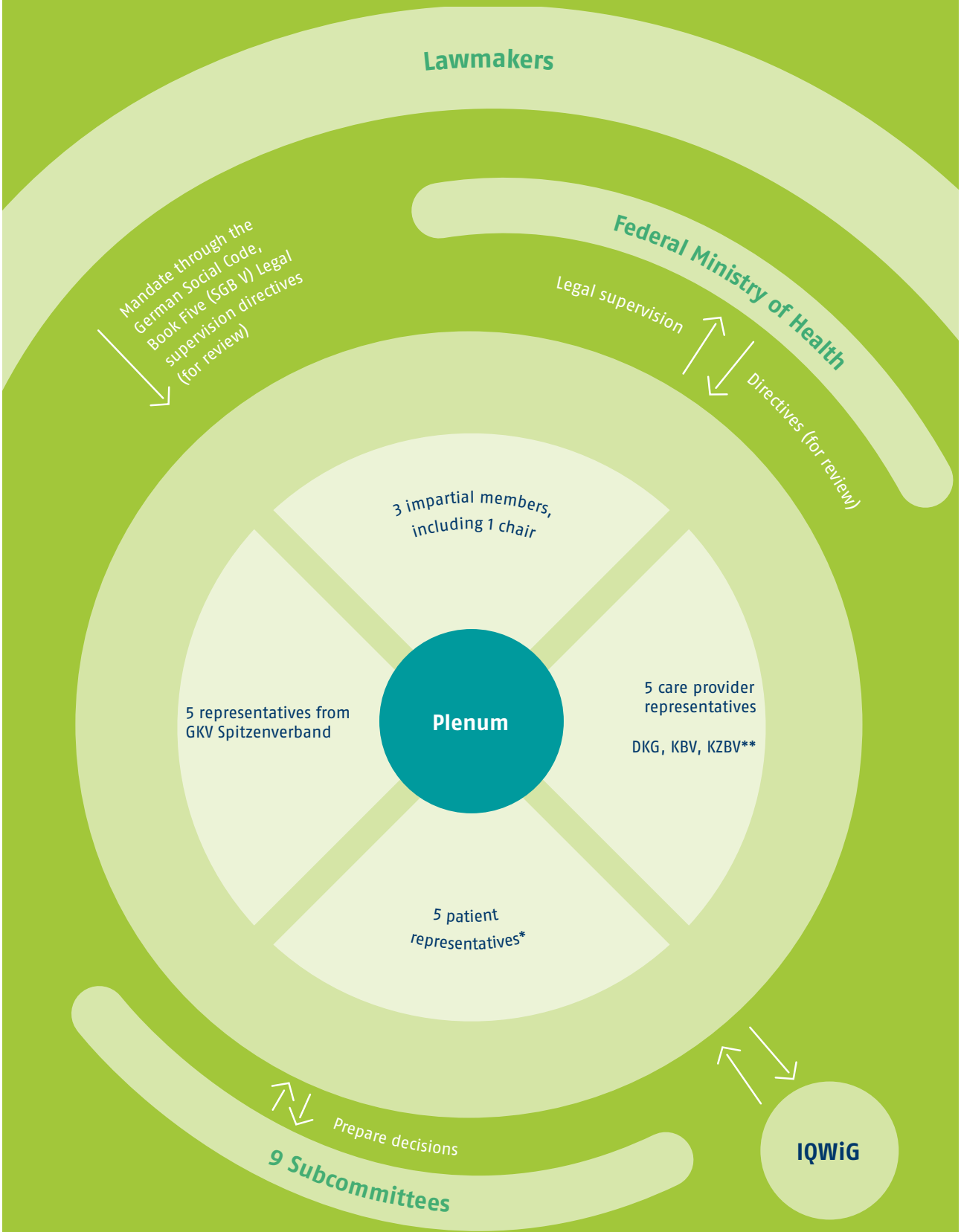
Any pharmaceutical product included in a reference price group is only reimbursed up to the reference price by the GKV-S. However, the manufacturer can still sell the product at a higher price, but the patient has to pay the difference.

Reference prices are determined in a complex, multi-phase procedure. They are calculated on the basis of the average prices of all the pharmaceuticals in the relevant group and other factors such as the required average daily dose, etc.

Federal Joint Committee (G-BA)

Highest decision-making body of the joint self-government of physicians, hospitals and health insurance funds in Germany.

It issues directives for the benefit catalogue of the GKV and thus specifies which services in medical care are reimbursed.



Source: IGES based on GKV-S

* Entitled to take part in discussions and submit petitions, but not to vote

** Care providers are entitled to vote solely on issues affecting their area of expertise. Otherwise these votes are allocated proportionally in accordance with the bylaws, section 14a, paragraph 3.

Abbreviations:
GKV-Spitzenverband = National Association of Statutory Health Insurance Funds
DKG = German Hospital Federation
KBV = National Association of Statutory Health Insurance Physicians
KZBV = National Association of Statutory Health Insurance Dentists

Rebate Contracts

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

The pharmaceutical manufacturer who is awarded the rebate contract for the generic will automatically supply all patients of this 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 exempted from the personal out-of-pocket payments.

When an active ingredient has lost 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.

Import Quotas

Prices for pharmaceuticals within the EU vary. Importers can buy pharmaceuticals at a cheap price in one member state and sell them in another member state. To save costs, a quota of 5% of all prescription pharmaceuticals dispensed in a pharmacy must be imported. Pharmacists are obliged to replace domestic pharmaceuticals with respective parallel imports to fulfill this quota, but the imported pharmaceutical has to be at least 15 per cent or 15 euros cheaper than the equivalent original German product. Furthermore, pharmaceuticals which are subject to rebate contracts cannot be replaced by imported pharmaceuticals.

Orphan Drugs

Early benefit assessment regulations also comprise orphan drugs, but some specific rules apply: a full benefit assessment is not required for orphan drugs that do not exceed a turnover of 50 million euros during a 12 month ambulatory care period for GKV patients. Only the degree of their additional benefit has to be proven, based on the assumption that orphan drugs have an additional benefit. In this case, the pharmaceutical manufacturer only needs to submit a reduced version of the dossier and benchmark the benefit of the orphan drug against the comparative therapy from the decisive phase III study. However, if the 50 million euros limit is exceeded, a full dossier is required.

Rules for the Prescribing Physician

The GKV uses a multitude of elements to make physicians prescribe fewer and cheaper medication, for instance, by granting incentives. The following procedures are used:

A. Personal Budgets

Each physician is allotted a personal budget for pharmaceutical prescriptions (Richtgrößenvolumen). The calculations for this budget are based on the prescribing data of similar patients. Physicians exceeding their personal budget by more than 15 per cent will be investigated and instructed to prescribe less. In the worst case, physicians exceeding their personal budget by more than 25 per cent could even be made liable.

B. Prescription Guidelines and Guideline Restrictions

The G-BA can issue guidelines for the prescription of costly pharmaceuticals. Furthermore, the G-BA can exclude specific pharmaceuticals from GKV coverage for certain indications. Physicians ignoring these guidelines are informed about therapeutic alternatives by the GKV funds, and ultimately risk being made liable for compensation.

C. Quota Rule for Prescriptions

Top selling groups of pharmaceuticals are subject to quotas. These quotas are set jointly by physician associations and GKV funds. Some quotas apply in specific regions in Germany only. Physicians are informed by their associations. For some pharmaceutical classes, quotas for prescribing specific active ingredients exist. In the State of Berlin, for instance, 70% of all prescribed SSRIs must either be citalopram or sertraline. The physicians can prescribe other SSRIs for the remaining 30%. Individual physicians are sometimes given an incentive to achieve specific quotas. Non-compliant physicians could face fee reductions and may also have to attend professional training on prescribing economically.

Hospitals in Germany

1,951
Total number of hospitals in Germany

498,718
Total number of hospital beds

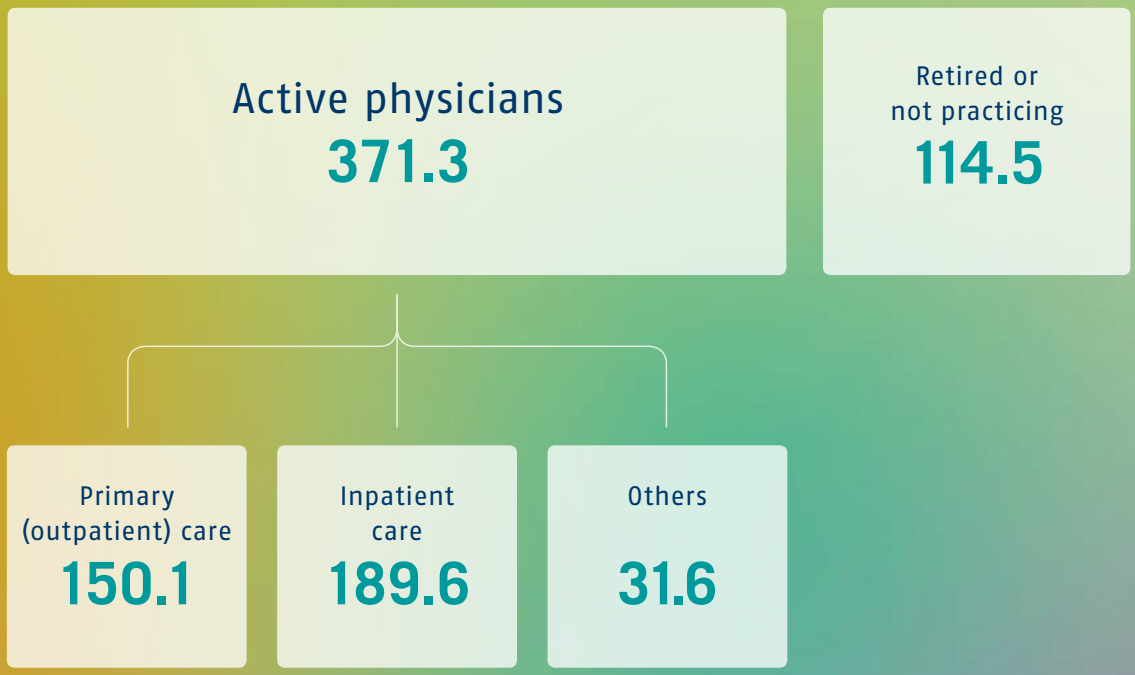
77.9%
Rate of hospital bed utilization

19,532,779
Total number of cases treated in Germany per year

880,519
Total hospital staff

Source: German Federal Statistical Office, data for 2016

Structure of the Medical Profession in Germany
(in thousands)



Source: IGES based on Bundesärztekammer (German Medical Association), data for 2015

Inpatient

Use of Pharmaceuticals in Stationary (Inpatient) Care

Pharmaceutical products used in inpatient care are not billed separately to the GKV fund. The GKV reimburses the entire treatment of the patient.

German Diagnosis Related Groups (G-DRG)

In the inpatient sector, the reimbursement of services for treating patients is based on the so called "German Diagnosis Related Groups" (G-DRG), a fee-per-case system. There are roughly 1,300 different DRGs in Germany. The DRG classification system uses case related coding rules that apply to diagnoses (ICD-10 German modification) and procedures (Operations and Procedure Codes (OPS)). With the DRG case-based flat rate, all costs related to the treatment and the hospitalization of the patient are covered, including pharmaceuticals. The G-DRG system's contents are revised annually by the InEK. Each DRG compensation amount is based on empirical data which is continuously collected from several hundred German clinics. There is a time lag between the availability of a new procedure code and an adequate DRG assignment. G-DRG updates conducted by the InEK are based on the above mentioned empirical data from previous years.

Additional Charges (Zusatzentgelt)

There are two ways to cover the costs of expensive drugs for inpatient care which cannot be remunerated by existing DRGs: The additional charges (Zusatzentgelt) and the NUB procedure (NUB: New Methods for Treatment and Screening).

In 2018, there are a total of 205 additional charges, some of which had to be negotiated for the individual hospitals. Hospitals and medical societies can apply for the application of such an additional charge. If appropriate, the InEK will create an additional charge on its own initiative. In most cases, the monetary value of the additional charge is based on empirical cost data supplied by reference hospitals.

New Methods of Treatment and Screening (NUB)

A second procedure for remunerating cost-intensive services is the NUB (New Methods for Treatment and Screening). This procedure is only open to technologies/ procedures that are considered new in Germany. Hospitals can file electronic requests to the InEK once a year to enquire whether the conditions for negotiations have been set for hospital-specific temporary extrabudgetary payments (NUB-payments). If the request receives a favorable reply, the hospital can enter into negotiations with the respective local healthcare payer. Each hospital must apply separately. The extrabudgetary payment, provided the application is approved, will only be available to the hospital that negotiated successfully.

Approved applications are subsequently monitored by the InEK. And at some point in the future, InEK will integrate the corresponding procedure into the standard DRG system. This procedure is widely used, but very often unsuccessful:
because the requests for NUB payments are rejected if the method at stake has already been included in an existing DRG or is not considered innovative. It should be noted that the InEK makes no decision on the actual amount of the extrabudgetary payment. This is directly negotiated between the successful hospital applicants and the GKV.

IGES Group

The Knowledge Corporation

Independent and innovative since 1980, IGES Group focuses on research, development and consulting for life sciences and health care.

CSG

CSG (Clinical Study Group) is a full-service contract research organization, offering services in planning, implementing and analyzing clinical-scientific studies.

IMC clinicon

IMC clinicon is a consulting and services institute for the hospital sector, providing in-depth data and analysis on German hospitals.

AiM

AiM (Assessment in Medicine) is a health-economic consulting agency for the medical device industry, dedicated to reimbursement programs. Health technology assessment dossiers are founded on qualitative and scientific methodologies.

HealthEcon

HealthEcon, based in Basel, Switzerland is a consulting firm for Health Technology Assessment, European market access and value strategy for the pharmaceutical industry with almost 40 years of experience.

iGES

IGES Institute is the core of the IGES Group. It offers comprehensive services based on expertise: studies, reports, publications, evaluations, concepts and strategies. Since its foundation, it has conducted over 2,000 research and consulting projects.

IGES Services

Health Economics & Outcomes Research

- Value demonstration
  - Dossiers for early benefit assessment and clinical evaluation of drugs
  - Health technology assessment (HTA)
- Health-economic evaluation

Real-world and care provision analyses

- Demand and access
- Quality of care
- Utilization and expenditure

Market analysis

- Assessment of inpatient and ambulatory sector potentials
- Competition and regulation analysis

Strategic consultation

- Pricing and market access
- Portrayal of individual product reimbursement pathways
- Assistance with review processes conducted by the Federal Joint Committee (G-BA)/Institute for Quality and Efficiency in Healthcare; consulting for new examination and treatment methods (NUB)

Glossary

DIMDI: Deutsches Institut für Medizinische Dokumentation und Information (German Institute of Medical Documentation and Information)

G-BA: Gemeinsamer Bundesausschuss (Federal Joint Committee)

G-DRG: Diagnosis Related Group (German Modification)

GKV: Gesetzliche Krankenversicherung (Statutory Health Insurance)

GKV-S: GKV-Spitzenverband (National Association of Statutory Health Insurance Funds)

HTA: Health Technology Assessment

InEK: Institut für das Entgeltsystem im Krankenhaus (Institute for the Hospital Remuneration System)

IQWiG: Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (Institute for Quality and Efficiency in Healthcare)

NUB: Neue Untersuchungs- und Behandlungsmethoden (New Methods for Treatment and Screening)

OPS: Operationen- und Prozedurenschlüssel (Surgery and Procedure Code)

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