REIMBURSEMENT OF PHARMACEUTICALS IN GERMANY

2020

Institute for Innovation Management in Health Care
I.f.G.V.

Dr. Alexander Wilke MBA, LL.M.

Innovative Pharmaceuticals

The Way for Pharmaceuticals into the German Market.

The Institute for Innovation Management in Health Care (I.f.G.V.)

About the I.f.G.V.

The I.f.G.V. is a private, non-profit research institute, working according to university criteria.

The I.f.G.V. cooperates strongly with health insurances, regulatory authorities, clinics and industry, primarily in the fields of healthcare management, reimbursement management, health care economics, development of health and disease management programs as well as market / patient access and benefit assessment of medical devices and pharmaceuticals.

The I.f.G.V. is accredited for the areas benefit assessments, individual contracting and pricing at the most governmental authorities in Germany, Austria and Swiss.

The I.f.G.V. has developed the value laboratory to deliver the highest levels of academic quality in the areas of value analysis, value-based pricing, value assessment framework and value strategy building. This ensures that the criteria of evidence-based medicine have been fully complied within the current benefit assessment process.

Main areas of activity of the I.f.G.V.

1. Complete Management of Benefit Assessments (AMNOG –> GBA) and Price Negotiations at GKV SV
2. Management of Orphan Drugs, Genetic Pharmaceuticals and Special Indication Products
3. Value Demonstration of Pharmaceuticals for Reimbursement
4. Pricing (value-based pricing) & Individual Product Reimbursement Pathways
5. Medical and HEOR - Value Management
6. Market Access & Patient Access for Pharmaceuticals
7. Disease & Patient Management Programs
8. Reimbursement Negotiation at Payer and Governmental Authorities
9. Development of Reimbursable Digital Health Solutions
10. Market Access Management for Inpatient and Outpatient Sector
11. Projects around Translational Medicine for Payer and Hospitals

The Leader of the Institute:

Dr. Alexander Wilke studied human biology with a focus on neurophysiology, holds a master's degree in health economics and health policy and holds a LL.M. degree for medical and social law. His expertise in market / patient access, HEOR and health policy has been developed in many large companies and institutes.

He now has around 20 years of experience in various market access and health policy positions in pharmaceutical / medical device and biotech companies. The focus of his work was the implementation of benefit assessment procedures for medical devices and pharmaceuticals as well as the introduction of the scientific health policy approach and the development of a scientific individual contract management between health insurers and industry.

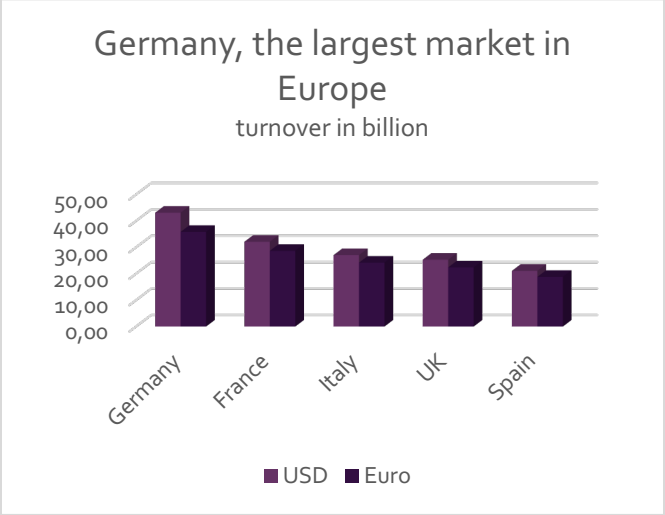
We hope that this brochure will help you take your first steps into the German market. As an accredited Institute at the HTA authorities, we have already been able to accompany many companies on their way to reimbursement.

It can be done!

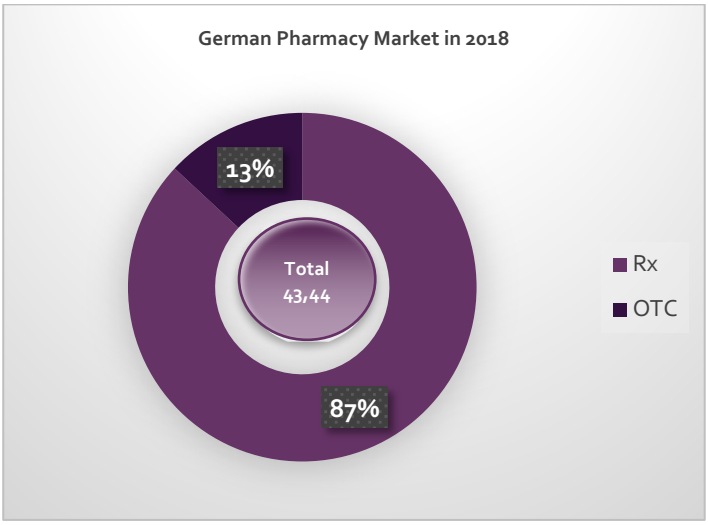
Welcome to Germany – Europe`s most Important Market for Pharmaceutical Products

Germany`s advantages for pharmaceutical products:

1) Market size
2) Reliable legal frameworks for approval and reimbursement
3) Quality and cost – effectiveness of its clinical research
4) Structured benefit assessment process
5) Face to face reimbursement price negotiation with GKV – SV
6) Special processes for orphan drugs, genetic products and other special products



Manufacturer turnovers (ex-factory price).



Total turnover of pharmaceuticals in German pharmacies.

The US has the largest market, second is China, third is Japan, and Germany hast the world`s fourth largest market.

I. European Regulatory System for Pharmaceuticals

>> The European system provides different routes for authorizing medicines <<

Regulatory procedure pathways:

The majority of medicines are authorized by national competent authorities (NCAs) in the member states. There are two NCAs for human drugs in Germany:

a) The Bundesinstitut für Arzneimittel und Medizinprodukte - BfArM (Federal Institute for Drugs and Medical Devices)
b) 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:

(1) 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.

(2) 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.

(3) 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.

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*
- *Free incentives (up to 100 per cent reduction)*
- *Assistance with the product information translation required for EU marketing authorization.*

Orphan Drugs:
The EU legislation provides incentives for pharmaceutical companies to develop orphan drugs. To qualify for these incentives, products must meet the EMA orphan drug 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 reduction*
- *EU – funded research sponsors may be eligible for EU and member state programs.*

II. Key Facts German Health System

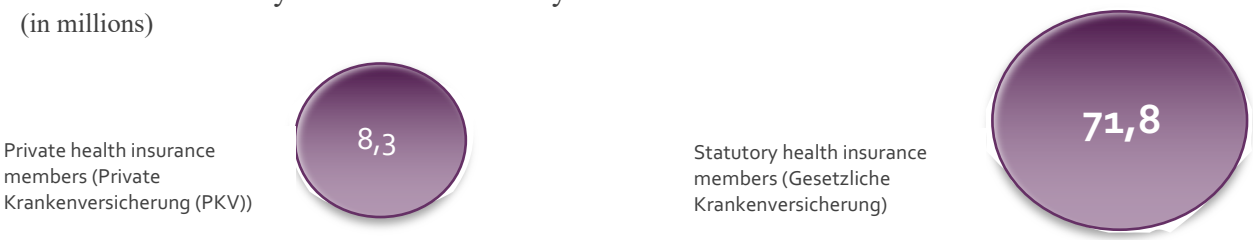
Key facts German health system:

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 who 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.

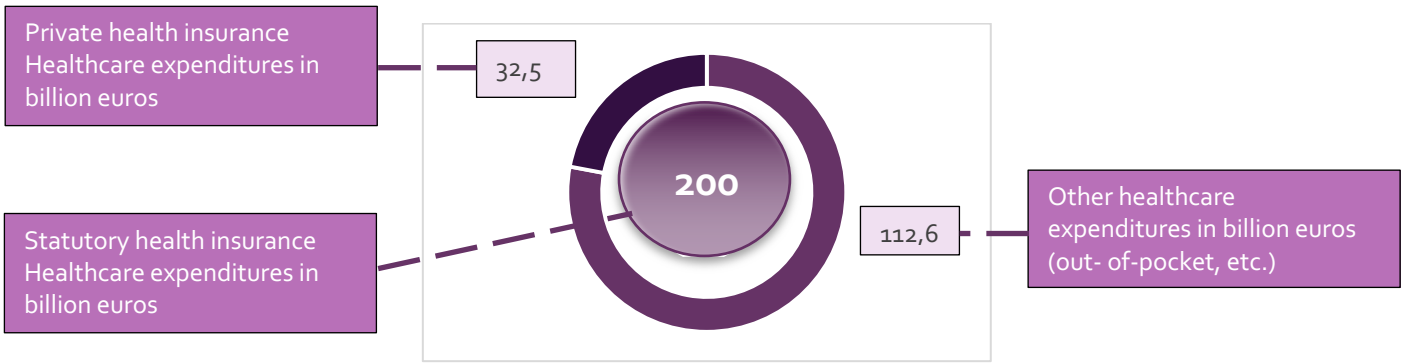
Top 5 largest Health Insurance Companies by Members:

Health Insurance Company	Number of Members
Techniker Krankenkasse, TK	9.730.640
Barmer GEK	9.345.712
DAK – Gesundheit	5.847.240
AOK Bayern	4.398.260
AOK Baden – Württemberg	4.227.700

Private and Statutory Health Insurances by Members:
(in millions)



Total annual healthcare expenditure in Germany:



III. Key Facts: Reimbursement Structure for Pharmaceuticals

Market Access Tip:

There are different pharmaceutical reimbursement pathways that must be used in outpatient care. At the developing of your market access entry strategy you should consider the following thoughts:

- *A) A crucial factor for the reimbursement of pharmaceuticals in Germany is whether it will be used:*
  - *a. Hospital sector → Inpatient sector*
  - *b. Ambulatory setting → Outpatient sector*
- *B) Competition and market environment*
- *C) National regulatory requirements*
- *D) Specific Benefit Assessment (AMNOG) requirements at Joint Federal Committee (GBA)*
- *E) Existing data quality for the pharmaceutical product*
- *F) Possibility of early pre AMNOG – contracting with payer*

Example: Price structure for a pharmaceutical product in Germany

>> The initial price for a product can be freely set by the manufacturer for a period of 12 months after market launch. This official price must be officially declared. After the 12 months period, the price must be negotiated with GKV SV after benefit assessment (AMNOG) {see chapter IV}

	Ex-factory price: (Herstellerabgabepreis (HAP))	**50,00 Euro**
+	**Wholesaler surcharge** (Großhandelshöchstzuschlag (3,15 % auf HAP + 0,70 Euro))	2,28 Euro
=	**Pharmacy purchase price** (Apothekeneinkaufspreis (AEP))	**52,28 Euro**
+	**Pharmacy surcharge** (Apothekenzuschlag (3 % auf AEP + 8,35 Euro))	9,92 Euro
+	**Emergency service surcharge** (Notdienstzuschlag) (0,16 Euro)	0,16 Euro
=	**Net - Pharmacy retail price** (Netto-Apothekenverkaufspreis (AVP))	62,36 Euro
+	**Value added tax** (VAT) Mehrwertsteuer (19 % auf Netto-AVP)	11,85 Euro
=	**Gross Pharmacy retail price** (Brutto-Apothekenverkaufspreis (AVP))	**74,21 Euro**
-	**Statutory additional payment of the insured** (Gesetzliche Zuzahlung des Versicherten (10 % vom Brutto-AVP))	7,42 Euro
-	**Statutory pharmacy discount** (Gesetzlicher Apothekenabschlag (1,77 Euro))	1,77 Euro
-	**Mandatory manufacturer discount** (Gesetzlicher Herstellerabschlag* (7 % vom HAP))	3,50 Euro
=	**Final insurance selling price (without rebate contracts)**	**61,52 Euro**

Prescription rules:

As a general rule, the GKV covers prescription only for medications which are used for treating diseases. Lifestyle medications are exempt of prescription and reimbursement. 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 or approved product is available for this indication
- using, it aims at treating a life threatening disease
- scientific data indicates good prospects of treatment success as well as a positive risk/benefit balance

Prescribing physicians:

Health insurance companies use various tools to reduce drug expenditure in Germany. Some of these measures directly target the prescribing behavior of physicians. From a market access point of view, these tools always must be considered and managed. Unfortunately, 17 regional physician associations (Kassenärztliche Vereinigungen) have to be observed individually, since each KV uses these tools differently.

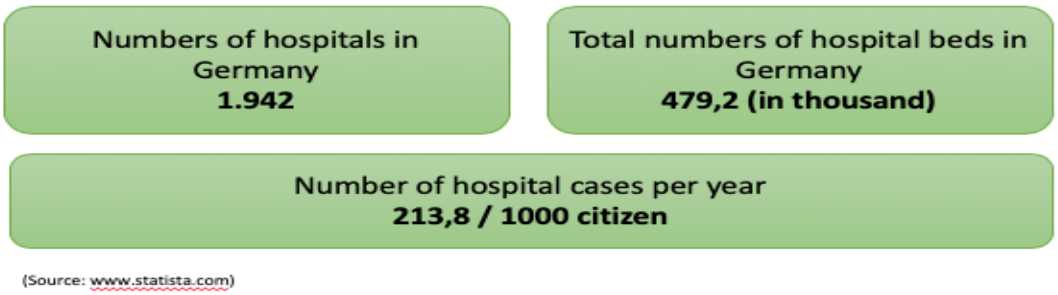
The three most popular tools:

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.

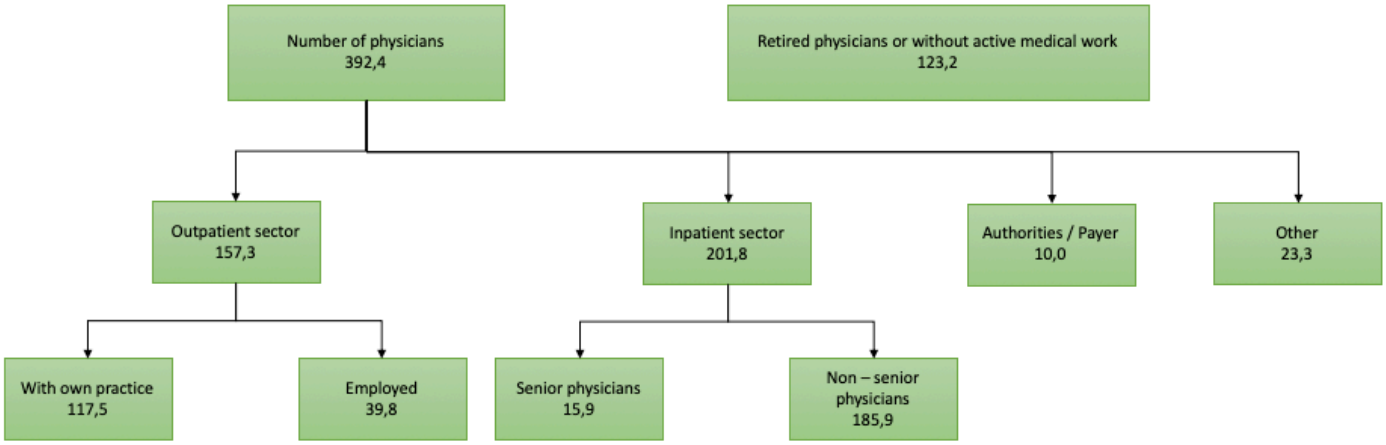
C. Quota rule for prescriptions:
Top selling groups of pharmaceuticals are subject to quotas. These quotas are set jointly by physician associations and GKV funds. Some quotas only apply in specific regions in Germany. Physicians are informed by their associations.
For some pharmaceutical classes, quotas for prescribing specific active ingredients exist. Individual physicians are sometimes given an incentive to achieve specific quotas. Noncompliant physicians could face fee reductions and may also have to attend professional training on prescribing economically.
Quotas are defined for indications, indication areas (AT) or products. (e.g. Biosimilars, Original Biologicals, SSRI, Oncology Products, SSRI etc.)

Overview inpatient sector:



(Source: www.statista.com)

Overview outpatient sector:



Structure of medical profession in Germany 31.12.2018 (in thousand)
(Source: www.bundesaerztekammer.de)

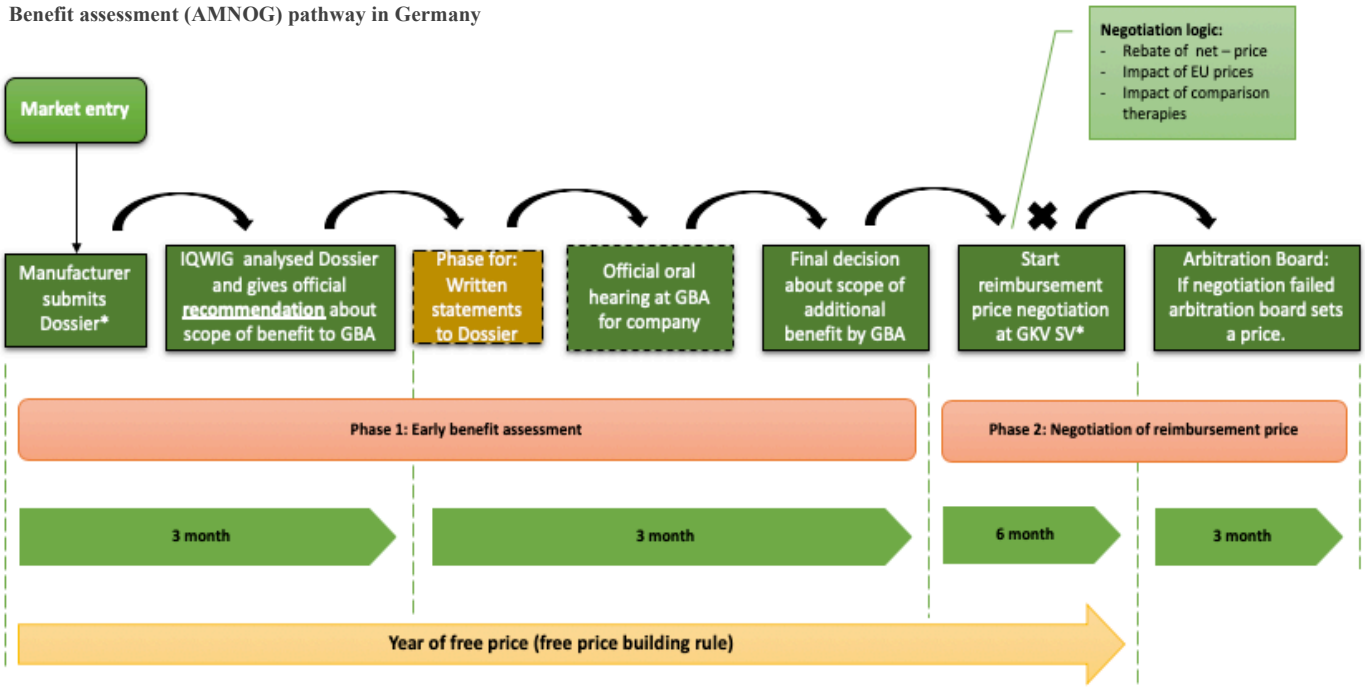
IV. Benefit Assessment for New Pharmaceuticals (AMNOG Process)

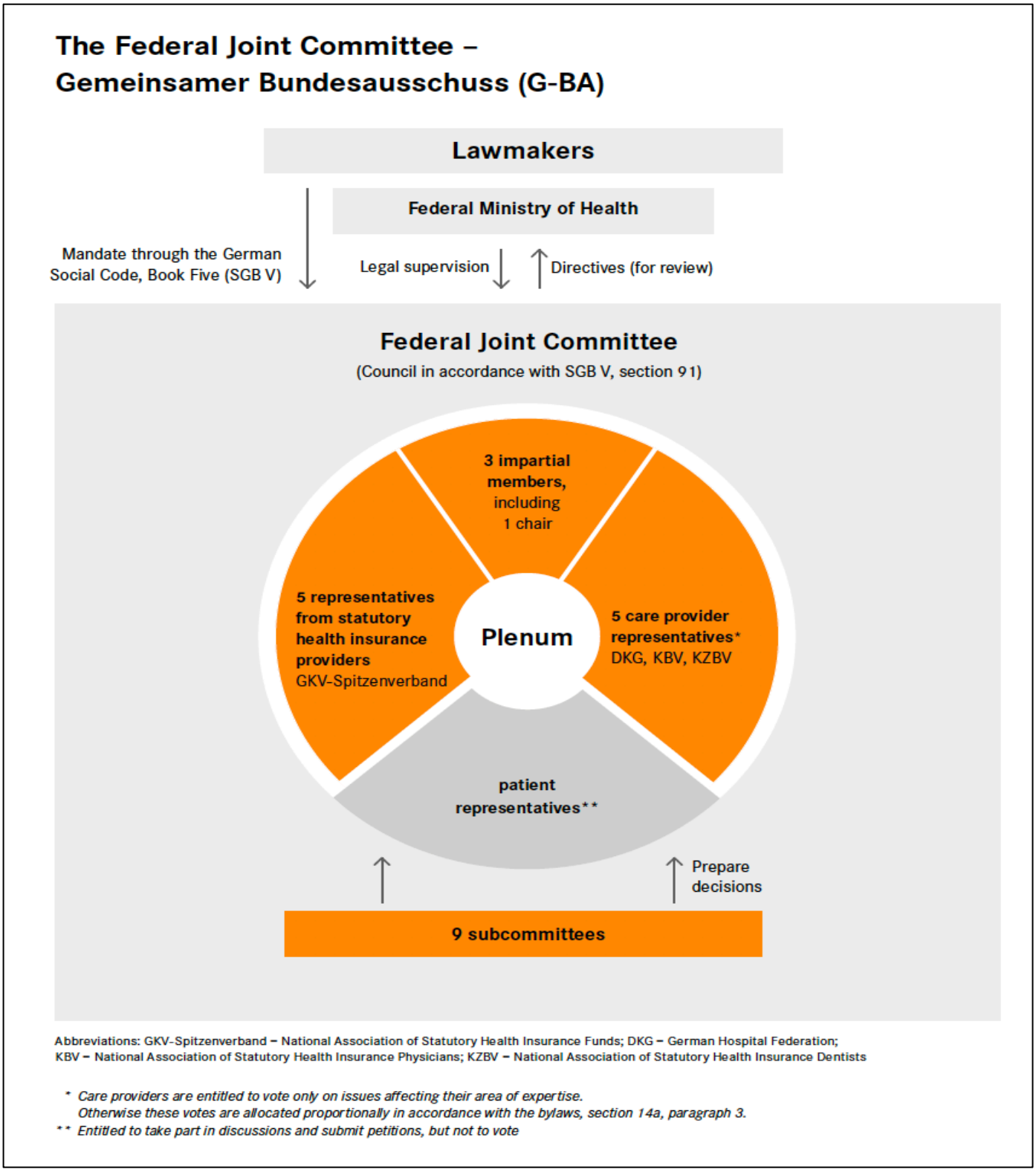
>> The way into the German market<<

<u>The German Benefit Assessment:</u>

In 2011 the AMNOG (Act on the Reform of the Market for Medicinal Products, Arzneimittelmarktneuordnungsgesetz) became effective and since then the pharmaceutical companies have to demonstrate an added benefit of a new pharmaceutical, a new combination or a new label versus the established therapies / comparison therapies or best supportive care. The scope of the added benefit (additional patient related benefit (!)) is the basis for price negotiations with the Head Organization of the German sick funds (GKV SV).

Benefit assessment (AMNOG) pathway in Germany





Structure of the Federal Joint Committee (www.g-ba.de)

Based on the best clinical evidence compared to comparator therapy {German term: "Zweckmäßige Vergleichstherapie"} (excluding orphan drugs), the GBA makes a value decision in the form of various ratings, that describe the scope of the patient-relevant additional benefit.

Health economic models (e.g. BIA`s) such as in the UK, as well as specific clinical endpoints, cannot be used and are not taken into account in the process.

The key words in the AMNOG process are:

- *Additional – patient related benefit vs. a comparison therapy*
- *Value decision-based on clinical evidence*

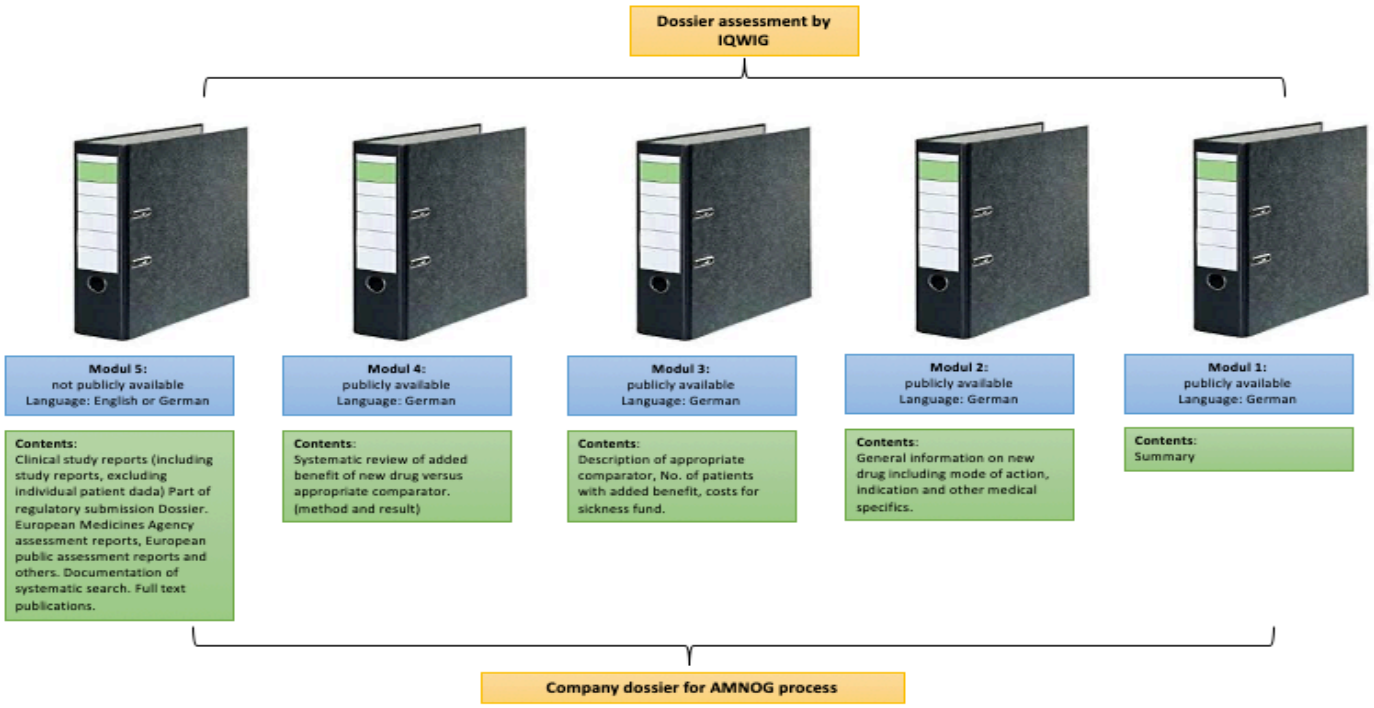
Special case Orphan Drug

- *Orphan drugs can be submitted with a reduced dossier*
- *Orphan drugs do not have to compare to a comparison therapy (German term: "Zweckmäßige Vergleichstherapie")*
- *Non – quantifiable additional benefit per law (GAB must assess the extent)*
- *If the product exceeds the 50 million turnover threshold (annualy), the manufacturer must submit a **full dossie**r to the GBA.*

The Dossier:

The dossier for the German benefit assessment places extensive data requirements on the entrepreneur. It should be noted, that the structure and the data to be transmitted are clearly defined and must be adhered. With the dossier, the entrepreneur must demonstrate the added value compared to the comparator therapy specified by the GBA. The data requirements, publications to be transmitted and other documents are increasing. In addition, the dossier places special requirements on the processing and presentation of the data. These can be found in detail in the current rules of procedure of the GBA and in the method paper 5.0 of the IQWIG (picture 1 below)

The German Dossier – structure and contents:



Dossier strategy:

- *Before you start with dossier writing → develop a clear dossier strategy*
  - *Argumentation flow*
  - *"Which argument when" (Optimal using of impacts of arguments / values regarding on the different stages of AMNOG procedure. {oral hearing; GKV negotiation}*
  - *Story telling: What is the overall message? What is the medical need? What is the health care need?*
  - *Additional data analysis*

Early advice meeting at GBA:
Before starting your activities, it is crucial to absolve an early advice meeting at GBA. At the early advice meeting, you can clarify the following topics:

a) *Is my evidence strong enough for a successful AMNOG procedure?*
b) *Which data do you need for your dossier?*
c) *What is your official comparison therapy? ("zweckmäßige Vergleichstherapie")*

The final Decision:

After submitting your dossier to the GBA, the IQWIG institute starts with analyzing and assessing. After three months (see page 7), the IQWIG officially announces its results and sends its recommendation about the scope of the additional benefit of your product versus comparison therapy to the GBA. **At this point in time it is only a recommendation!**

At next step at the procedure the dossier with IQWIG assessment is published on GBA homepage. KOL`s, and other organizations have now the opportunity to comment → written statements.

After the "written statement" phase, the manufacturer gets an invitation for an official oral hearing at GBA.
This is from my perspective the **most important touchpoint with GBA! Use this opportunity!**

If you have absolved the official oral hearing, the GBA makes his final decision about the scope of your patient related added benefit of your product (end of the 6th month after dossier submitting, see page 7).

Official oral hearing:

The official oral hearing at GBA gives the manufacturer the chance to defend his data and positions to the product. Otherwise, members of IQWIG, GBA, GKV SV and other associations can ask question and discuss specific question around the product. Main topics are medical question, question around study design, statistics, medical need or health care need. PLEASE → No Marketing Messages!

In various cases GBA decided differently to the IQWIG recommendation (higher scope of benefit).

*The official oral hearing is the last point in time for the manufacturer to bring **new data** in the process.*

Important to know:

- *Max. 5 members from the company can participate*
- *The team leader can hold a short keynote (use it for positioning)*
- *You need experts on your side (statistician, study / dossier expert, medical expert)*
- *Have a strategy and a **storybook!***

Atmosphere at oral hearing: Court house

Be careful what you say, at the official oral hearing is written a "word – protocol". This protocol is published after the process on GBA homepage.

Extent of Additional Benefit:

The relevant endpoints for the benefit assessment in Germany are defined in the AM-NutzV as patient-relevant endpoints mortality, morbidity, quality of life and side effects. Patient-relevant endpoints are derived from the disease and the associated symptoms and consequences as well as the therapy goals. No data dimensions or the not fulfilling of the AMNOG specific data requirements can reduce your overall outcome.

Examples:

- EQ5D is one of the most used tools for quality of life measurement. Based on rules of procedure of GBA and IQWIG paper, GBA prefers health related quality of life tools. It could be, that EQ5D is not specific enough.
- PFS is in the most countries well accepted. At GBA process, it is declared as combine endpoint. GBA prefers OS.

Quality of evidence:
The study endpoints are weighted according to the following system.

- Proof ("Beleg")
- Indication ("Hinweis")
- Hint ("Anhaltspunkt")

The individual parameters provide information about the certainty of results. The basis for the assignment is the methodological structure of the study, the statistics and much more.

Extent of Additional Benefit:

After the oral hearing, the GBA makes his final decision about the scope of the additional patient – related benefit of your product versus your comparison therapy.

IQWIG assessment / recommendation + oral hearing = extent of additional benefit

Grading:

Translation	Impact (1best / 6worst)	German Term
Major additional benefit	1	Erheblicher Zusatznutzen
Considerable additional benefit	2	Beträchtlicher Zusatznutzen
Minor additional benefit	3	Geringer Zusatznutzen
Non – quantifiable additional benefit	4	Ein Zusatznutzen kann vorliegen, ist aber aus den Daten nicht quantifizierbar
No additional benefit	5	Kein Zusatznutzen belegt
Less benefit than the comparative therapy	6	Nutzen ist geringer als der Nutzen der zweckmäßigen Vergleichstherapie

>> The extent of the additional benefit is of significant importance for price negotiations. <<

V. Reimbursement Price Negotiation at GKV SV

<u>The price negotiation at GKV SV:</u>

The GKV SV is the head association of all health insurance companies (without the private insurance companies). At the reimbursement price negotiation, you negotiate a reimbursement price for Germany, which works for the private insurances too. In the course of 6 months, 4 (in exceptional cases 5) negotiation meetings take place at the GKV SV in Berlin. Typically, 5 participants from the company and 5 participants from GKV SV sit at the negotiating table.

Overall outcome:

The final outcome of the negotiation is a reimbursement price for your product, fixed in a contract based on social law codex § 130 b SGB – V.

The most influencing factors for reimbursement price negotiation:

A) The extent of your additional benefit, based on GBA decision
B) EU reference prices
C) Prices of comparison therapies

Please note:
The overall intention of the price negotiation is the negotiation of a rebate of your current reimbursement price.

<u>Prepare for negotiation:</u>

a) Build a negotiation team:
- *Experienced negotiation leader*
- *Dossier / medical specialist*
- *Experienced lawyer*
- *Observer*

b) Develop a strong and clear negotiation strategy
- *Story book*
- *Offer cascade*
- *Argumentation chains*
- *Value house*
- *Communication strategy*
- *Objection handling*
- *Develop a negotiation strategy*
- *Develop different scenarios for possible contractual designs (e.g. timeframe, volume etc.)*
- *Consider patient support programs, or early identification programs as part of your negotiation*

c) Plan enough meetings (before negotiation meeting and after)
d) Simulations:
- *Coach your team in regular simulation with experienced GKV SV negotiation specialists*

e) Agree pricing range and negotiation range with your management

Last chance arbitration board:
If the manufacturer and the GKV SV cannot agree on a reimbursement price, the arbitration board is called. The impartial chairperson of the arbitration board decides on the amount of the reimbursement price by an arbitration award. (Complex process)

One example for new law driven regulations at AMNOG process:

Based on the law for more security in drug supply, the GBA can decide, especially for orphan drugs and other special medical therapeutics (e.g. genetic medications, special oncology medications), that the manufacturer must generate additional data in German expert centers (Real World Data). For this time, the manufacturer gets an "approval under condition / requirement". (Not to be confused with the regulatory approval of the EMA)

The study design for the additional data generation will be developed in cooperation between GBA and manufacturer.

This has various consequences for the reimbursement amount negotiation!

This potential "risk" of additional real-world data generation must be part of your AMNOG strategy.

The I.f.G.V. institute has developed a risk matrix to assess this risk and the implications for your AMNOG process and for your negotiation, based on your indication, product and data.

For more detailed information, please get in contact with:
Dr. Alexander Wilke from I.f.G.V. is at your service (alexander.wilke@ifgv-net.de)

VI. Opportunities for Contracts with Health Insurance Companies

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.

Tactical opportunities of rebate contracts:

- *Management of parallel imports*
- *Prescribing secureness for physicians*
- *Preferred provider status at health insurance companies*
- *etc.*

Pre – AMNOG contracts:
In some cases, it may make sense to conclude a discount contract with the health insurance companies when submitting the dossier to the GBA.
Contract duration: until the first round of negotiations according to GKV SV.
The advantages of such a pre-AMNOG contract must be assessed individual, based on product and indication.

Added value contracts (§ 140 SGB V):

Added value contracts offer the manufacturer contracts with health insurance companies to conclude innovative care solutions. Depending on the number of contractual partners, a distinction is made between one-sided or more sided contracts.

Typical contract partner constellations:

- Company →Health insurance company →Hospitals (Inpatient sector) or physicians (Outpatient sector)

- Company → Health insurance companies → Associations of physicians (Kassenärztliche Vereinigungen)

VII. Pharmaceuticals in Stationary (Inpatient) Care

Reimbursement of pharmaceutical products in inpatient (hospital) sector:
Usually pharmaceutical products in the hospital sector are not separately reimbursed by health insurance companies. They are part of an overall treatment pathway budget. (That means, the GKV SV reimburse 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 (defined as treatment pathway). 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 2019, there are a total of 215 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.
There are some tools existing how you can support hospitals at creating an additional charge.
Another opportunity are contracts between hospital and manufacturer.

New Methods of Treatment and Screening (NUB):

An alternative 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.

With this procedure, too, companies can use their expertise to help clinics with the application. In any case, a NUB application should be made available to the medical companies upon entry into the market.

Epilog:
We have taken the greatest possible care when creating the brochure. We hope you forgive any small mistakes. It is almost impossible to incorporate every detail and every possible strategy. However, we hope that this brochure will give you an overview about the possible reimbursement pathways in Germany for pharmaceutical products.
We have tried to incorporate our experience from our many managed AMNOG processes and negotiations through practical tips.
Please note that there are frequent changes to the rules of procedure of GBA at the moment!

Our experts from I.f.G.V. are available at any time for detailed information.

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Please note. From the I.f.G.V. is the Brochure "Reimbursement of Medical Products in Germany 2020" available too.

Glossary:

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

EBM: Einheitlicher Bemessungsmaßstab (Uniform Evaluation Scale)

G-BA: Gemeinsamer Bundesausschuss (Federal Joint Committee)

G-DRG: German Diagnosis Related Groups

GKV: Gesetzliche Krankenversicherung (Statutory Health Insurance)

HTA: Health Technology Assessment

IGeL: Individuelle Gesundheitsleistungen (Individual Healthcare Services)

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)

PKV: Private Krankenversicherung (Private Health Insurance)