Preview

iGES Pharma

Reimbursement and Pricing of Pharmaceuticals in Europe

2026

Reimbursement and Pricing in Europe

Germany

84.5

Population (in millions)

Source: Eurostat, data for 2023

766

Hospital bed density
(beds per 100,000 inhabitants)

Source: European Commission, data for 2023.

€ 47,815

GDP per capita

Source: Statista: Combined GDP per capita for the largest European economies in 2024.

€ 4.3

Total GDP (in trillions)

Source: Statista: Gross domestic product at current market prices of selected European countries in 2024.

$ 69.8 / € 64.5

Pharmaceutical Market in 2024 (in billions)

Source: IQVIA MIDAS, MAT December 2024. Conversion of US dollars to euros based on the average annual exchange rate for 2024.

The population of Germany is approximately 84 million. 73.6 million citizens are covered by statutory health insurance (Gesetzliche Krankenversicherung – "GKV") and approximately 8.7 million are covered by private health insurance (Private Krankenversicherung – "PKV") including citizens insured via state aid. The aim of this document is to explain the reimbursement system for patients covered by the GKV.

Major Legislation

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

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

Decision-Makers

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

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

Statutory Health Insurance in Germany

GKV is provided by approximately 100 statutory health insurance funds. These GKV funds provide comprehensive healthcare. The GKV is a compulsory insurance system which may only be terminated in favor of the PKV if certain requirements (annual income, liberal profession, etc.) are met. Health insurance is mandatory for all German citizens.

5 Largest Statutory Health Insurance Funds by Members in m:

Techniker Krankenkasse, TK	11.6
Barmer	8.5
DAK Gesundheit	5.5
AOK Bayern	4.6
AOK Baden-Württemberg	4.6

Source: Krankenkassen.de , Data for 2024

Prescription and Reimbursement of Pharmaceuticals

A crucial factor for the reimbursement of a particular medicinal product is whether the product will be used in an inpatient (hospital) or outpatient (ambulatory) setting.

Reimbursement of Pharmaceuticals in Primary (Ambulatory) Care

Scope of GKV Benefits and Patient Co-Payments

As a general rule, the GKV solely covers prescription-only drugs. Certain pharmaceuticals, such as life-style drugs (for instance for the treatment of hair loss) are not covered. 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 12 and for the treatment of some chronic conditions in adults. Patients have obligatory co-payments ranging from between 5 euros and 10 euros for each prescription. Drugs which are priced 30% below the reference price (see below) may be excluded from co-payments.

Off-Label Use

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

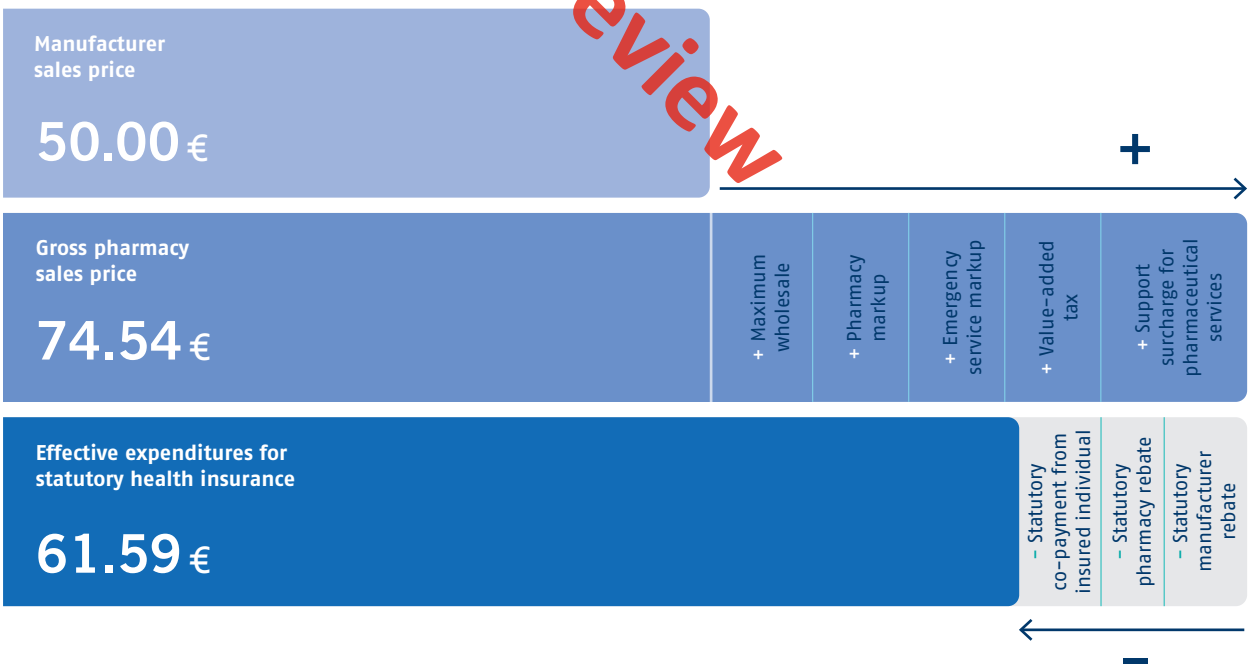
Ex-Factory Price

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

Mandatory Rebates

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

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



Source: IGES based on ABDA (Federal Union of German Associations of Pharmacists), Zahlen, Daten, Fakten 2024, page 36

Benefit Assessment of New Pharmaceuticals

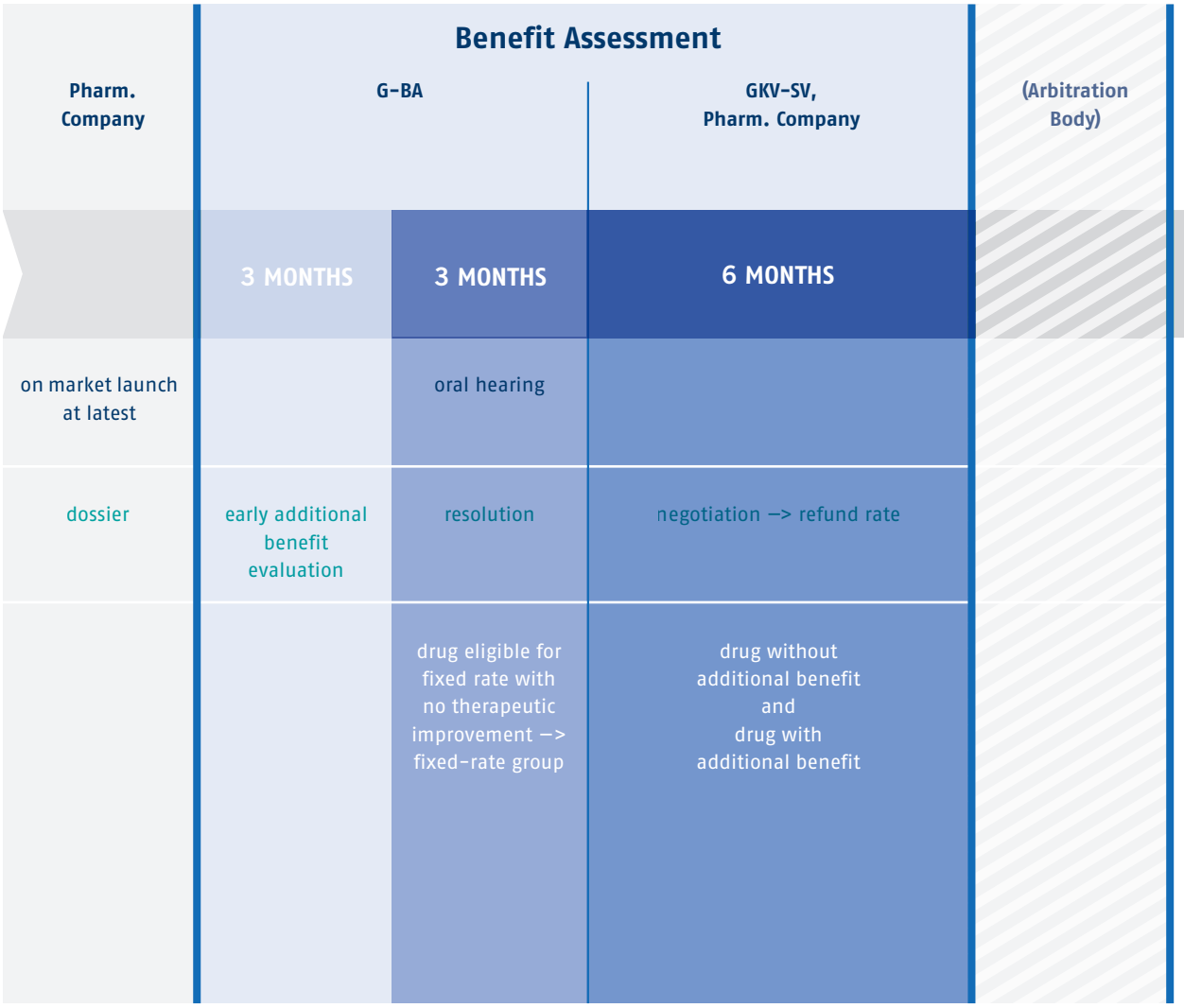
As described above, the pharmaceutical manufacturer is initially allowed to set the ex-factory price for a pharmaceutical product for a period of 6 months following market launch. After this period, the reimbursement price is negotiated on the basis of the pharmaceutical product's additional benefit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

Obligation to Collect Real World Evidence Datas

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

Benefit Assessment Evaluation of New Pharmaceuticals Timeframe

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



Source: IGES based on GKV-SV

Exemption of Antibiotics of Last Resort from Early Benefit Assessment

Since 2020, antibiotics of last resort (also called reserve antibiotics) can be exempt from the German benefit assessment. The manufacturer has to submit a formal request three months before launching the antibiotic. In case of an exemption, antibiotics of last resort are not subject to price regulation. However, hospital antibiotics must undergo the regular procedures for reimbursement in inpatient care.

Introduction of Confidential Prices

Previously, reimbursement amounts in Germany were publicly available, meaning that actual German prices could be used as a global reference. Since January 1, 2025, confidential reimbursement amounts have been possible in Germany if the drug in question is a novel drug being marketed in Germany for the first time and if the pharmaceutical company is actively conducting research in Germany.

Price Negotiation

If an additional benefit has been identified, the GKV-SV initiates negotiations with the pharmaceutical manufacturer regarding a mark-up on the price of an equivalent comparable therapy. If additional benefits compared to the expedient comparative therapy cannot be proved, the product is allocated to a reference price group with comparable active ingredients. If no such reference price group exists, the GKV-SV and the manufacturer negotiate a refund rate which does not exceed annual therapy costs more than the equivalent comparable therapy does.

Rebate Contracts

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

A pharmaceutical manufacturer who is awarded a rebate contract for a generic will automatically supply all patients of a particular GKV fund. In other words, pharmacies may only dispense generics for which rebate agreements are in effect. Software programs guide physicians in prescribing the correct generic, i.e. which is covered by the respective patient's GKV fund rebate contract. Patients benefit from rebated generics as they are exempt from personal co-payments.
When an active ingredient no longer has its patent protection, physicians can either prescribe the original brand, a branded generic or the generic name of an active ingredient. If generic versions of a prescribed active ingredient are available, pharmacists are legally obliged to dispense a generic version (generic substitution = aut-idem-rule). However, if a pharmaceutical product containing the prescribed active ingredient is subject to a contractual rebate agreement between a GKV fund and the marketing authorization holder, pharmacists are obliged to dispense the rebated pharmaceutical.

Orphan Drugs

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

Reference Pricing within Germany

Reference prices refer to the upper price limits for reimbursement, which have been determined by the G-BA and the GKV-SV for groups of similar or therapeutically comparable active ingredients. In Germany, reference price groups cover most generic drugs as well as patented pharmaceuticals if three or

About IGES Pharma

IGES Pharma is dedicated to biopharmaceutical companies. We provide specialized research and consulting services for innovative pharma and biotech companies. Our experts combine their skills to enable innovative medicines to successfully access the European market. Through our offices in France, Germany, Italy, the Netherlands, Spain, Sweden, Switzerland and the United Kingdom, we provide biotechnology and pharmaceutical companies from around the world with competent, pragmatic and rapid support.

Our specialists help to ensure that innovative medicines are made available to patients in Europe quickly and without obstacles. We offer customized solutions for market access in the entire biotech and pharma sector.

Decades of experience in the fields of clinical research, reimbursement and market access, established cooperation with regulatory authorities and payers, as well as pragmatism, unconventionality and speed are the hallmarks of our work. From selective, strategic support to multinational product launches – we are proud of our portfolio of successfully completed projects.

Capabilities

To overcome your market access challenges, we leverage all of our capabilities. We provide solutions by bundling products into capabilities and offering the full range of know-how, expertise and experience needed to ensure your success. At IGES, we recognize that every product is unique and there is no one-size-fits-all approach. Instead, we optimize patient access by tailoring our solutions to each product and its individual strengths to address local and global challenges.

Strategy

For biopharma inventors, navigating the ever-increasing complexity of market access in Europe is a significant challenge. Keeping on top of changes in the regulatory system, accounting for uncertainties such as labeling assumptions and their impact on time to market, and meeting the increasing evidence requirements of HTA authorities are just some of the challenges to be met to ensure successful commercialization of pharmaceutical products in Europe. IGES can help you cut through the complexity and find the right path to market with our extensive market access experience. We can map out the steps necessary to achieve your goal, right down to the implementation of the required activities. Because IGES provides operational support throughout the market access process, we know what it takes to decide on scenarios and plan your activities.

Pricing and Reimbursement

Setting the right price and ensuring patient access are critical to the commercialization of your pharmaceutical product. IGES can analyze patient pathways both quantitatively and qualitatively to understand their position within their respective care setting. In this way, barriers to access can be identified and removed. We can also support you at an early stage in creating predictive models to derive price estimates for your product or accompany your price negotiations on site by conducting the necessary research, defining a strategy, training you or even participating in the negotiations.

Health Technology Assessment (HTA)

The holistic processing of HTA applications is a core competence of IGES with the experience of more than 150 fully developed dossiers successfully submitted by our clients. Our efforts are focused on adequately capturing the value of your pharmaceutical product. By expressing its full potential in the respective HTA process, we ensure that we create a solid basis for meeting your price expectations. We take care of the communication with the authorities, compile the necessary documents and information and handle the submission of the assessment documents. IGES also prepares written statements and takes part in or prepares you for oral hearings.

Stakeholder Engagement

Involving the various stakeholders in the healthcare system when planning the launch of a pharmaceutical product is crucial. IGES can work on your behalf with all relevant stakeholders such as physicians, payers, patient organizations or health authorities. Thanks to our many years of experience, we can draw on a reliable network of experts and contacts to support you in setting up committees, background discussions or other discussion platforms.

Biostatistics

Our dedicated biostatistics team has extensive experience in the statistical analysis associated with bringing

innovative medicines to market. Using data from clinical trials, our team can perform the necessary post-hoc analyses for local HTA submissions, as well as network meta-analyses, indirect comparisons or surrogate validations.

Health Economic Modeling

To understand the value of your pharmaceutical product, it is important for health authorities to relate the clinical benefits to the costs and compare them with the current standard of care. Creating fit-for-purpose health economic models is one of IGES' core competencies. In addition to creating the model itself, we can also support you in identifying the relevant clinical and economic evidence through systematic literature searches. We guide you through the decision-making process to achieve your optimized outcomes models.

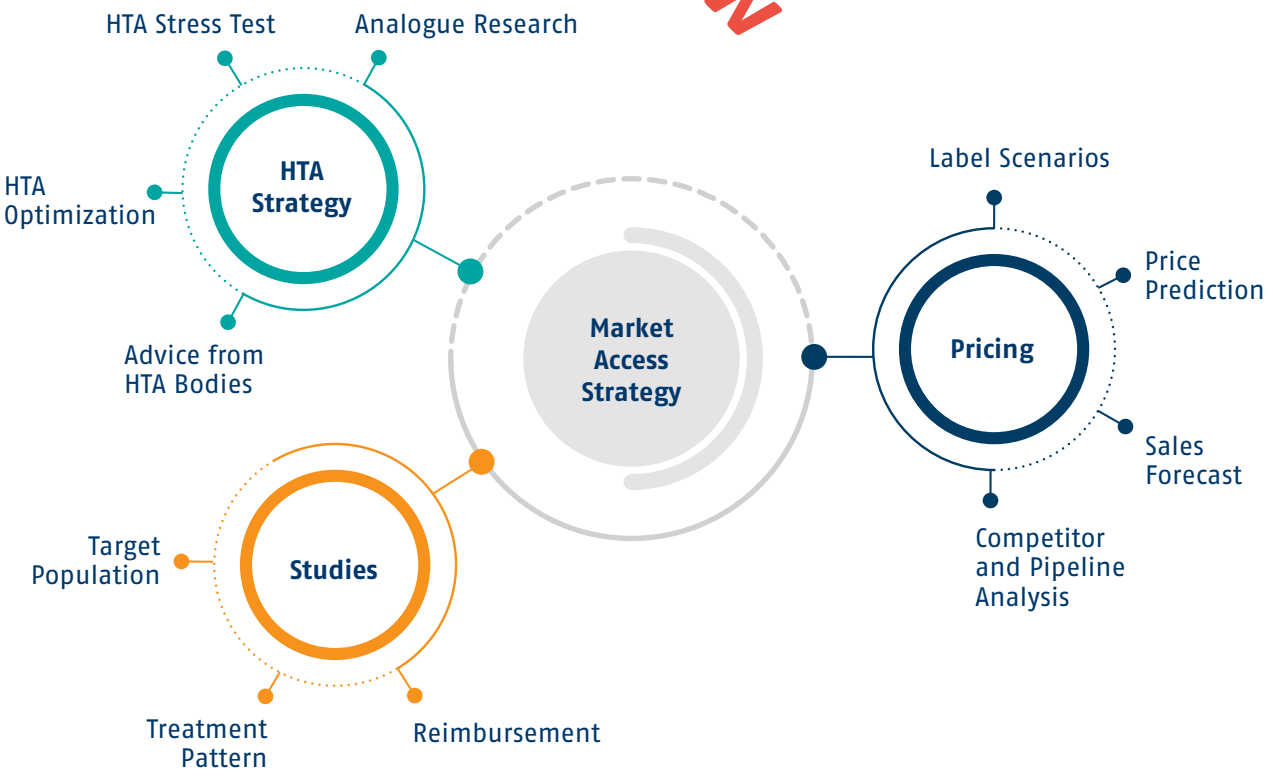
Health Services Research

To effectively integrate innovative medicines into their specific healthcare context, it is essential to learn from a patient-centered perspective how healthcare services are organized, delivered and used. IGES has many years of experience in the design, development and reporting of studies in the field of health services research, as this area has traditionally been one of the core areas of IGES. We regard the field of health services research as an analysis of health care under everyday conditions and thus as a complement to clinical research. We can advise you on the choice of an appropriate quantitative or qualitative methodological approach, provide you with relevant data or even make our own data collection available to you. Project results can be published e.g. in the form of scientific publications, expert opinions and white papers to promote dialog and debate on conceptual and normative issues related to health and healthcare. The results can also be used for internal strategy development in order to make important decisions on the basis of substantiated information.

Real-World Evidence

Real-world evidence data is becoming increasingly important for HTA agencies. This is particularly true for medicines that carry an early evidence package or are developed for rare indications. In these cases, the responsible HTA agencies can request additional data.

The collection of real-world data can be done as a proactive measure to enrich your HTA application or as a reactive measure as a requirement of the local HTA process. In both cases, IGES can support you in the collection of real-world evidence: from study design, study site recruitment and data collection to biostatistical analysis and presentation and submission of results to the HTA process. With our in-house CRO and biostatistics teams, we can support you every step of the way.



Solutions

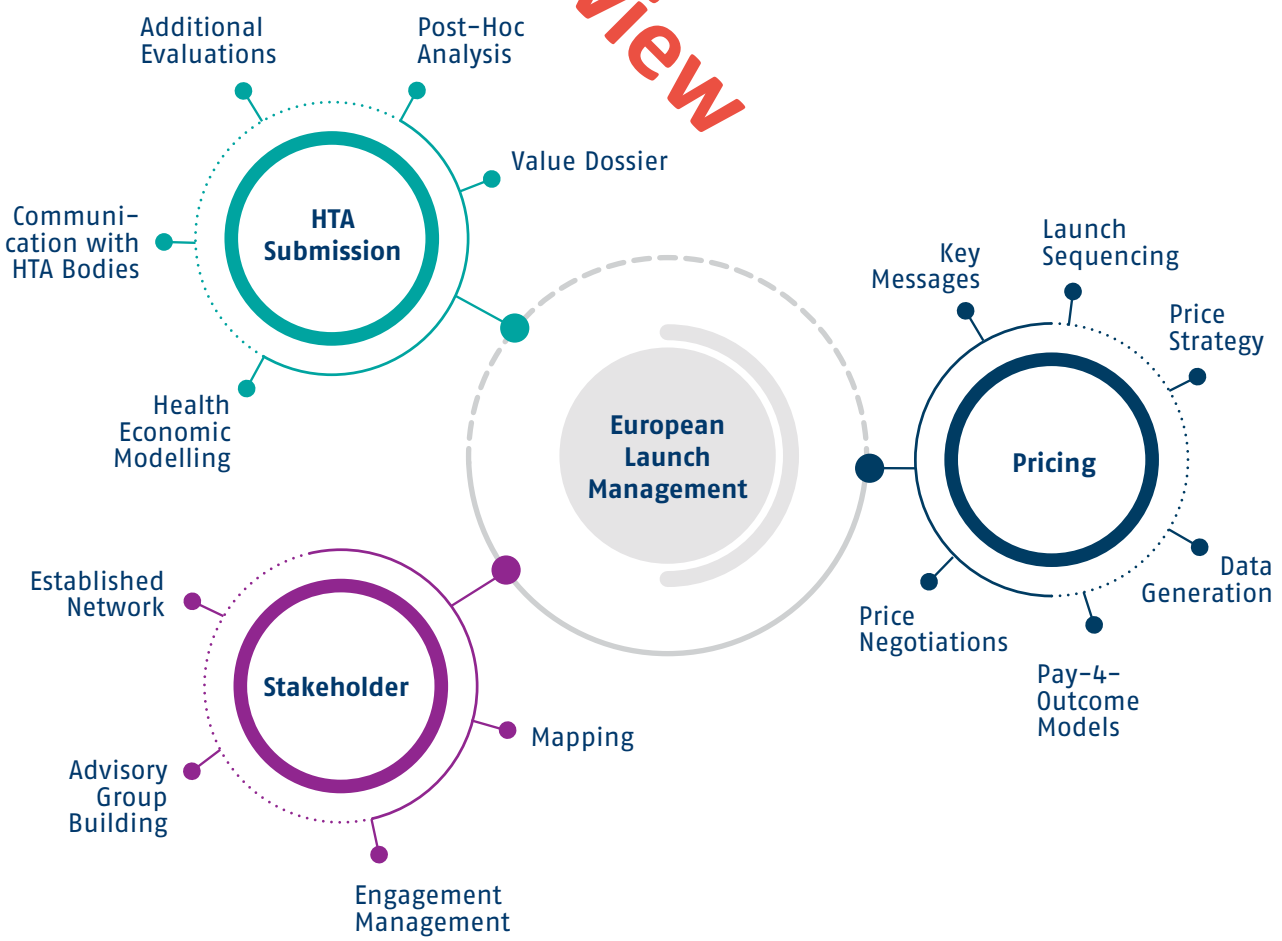
We provide solutions by applying products in the form of capabilities and providing the full range of know-how, expertise and experience required for your success. IGES Pharma's capabilities are at your disposal to overcome your market access challenges.

At IGES, we understand that every product is unique and there are no off-the-shelf solutions. Instead, we optimize patient access by tailoring our solutions to each product and its individual strengths to overcome local and global challenges.

Market Access Strategy

The increasingly complex market access in Europe places high demands on pharmaceutical companies. Despite all the complexity, successful market access in Europe is crucial for commercial success.

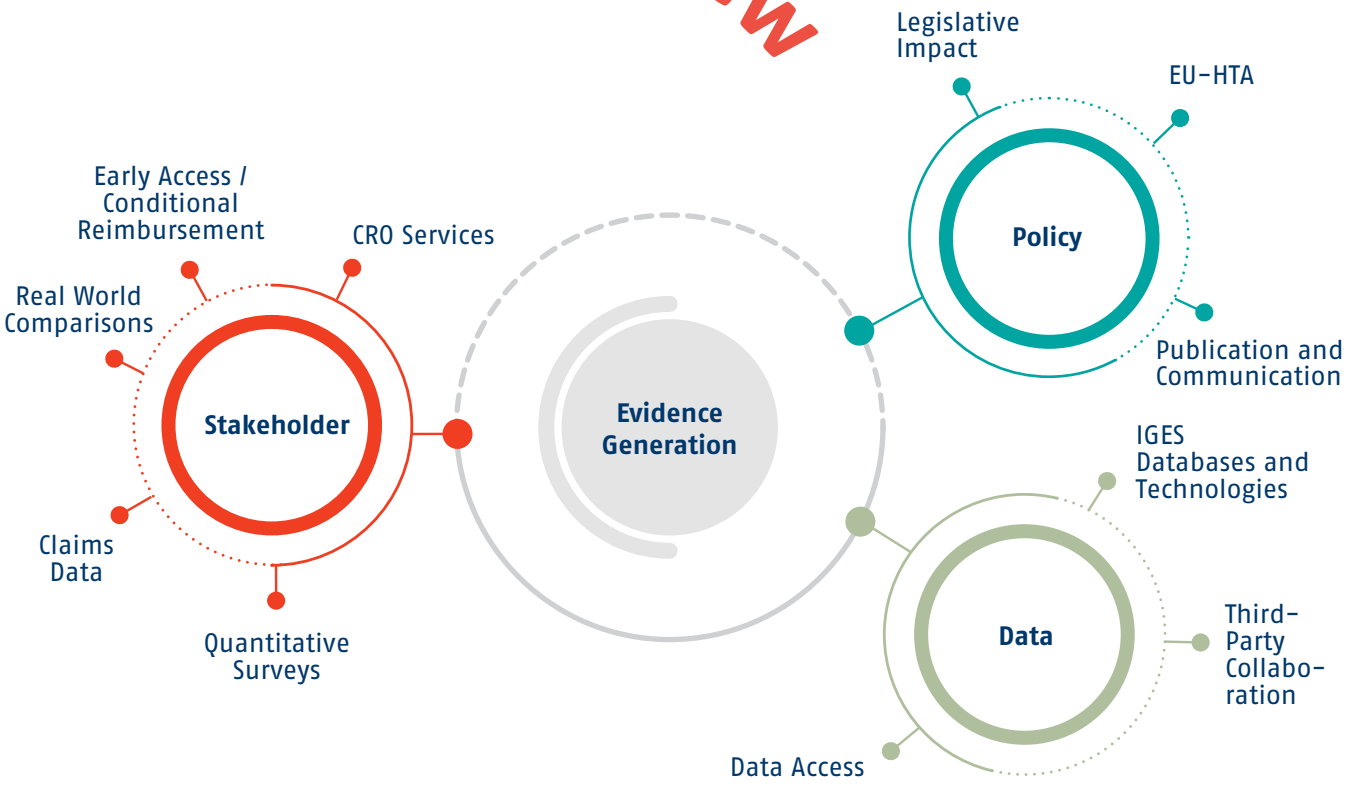
IGES can help you cut through this complexity with our extensive market access experience. We work with our clients every step of the way, from developing evidence generation programs that comply with European HTA requirements, to accurately assessing the commercial potential of products, including continuous optimization of the market access strategy, to product launch and beyond. As IGES provides operational support throughout the market access process, we know what is important when deciding on scenarios and making key business decisions.



European Launch Management

The number of biotech therapeutics being launched has been increasing for years and now accounts for a significant proportion of new product launches. Gene therapies open up completely new treatment options and have the potential to cure diseases that until recently could not be treated causally. With decades of experience working with top biopharma companies, IGES Pharma is ideally positioned to support such innovative therapies. In addition, IGES has developed a customized range of services and processes specifically for clients with very lean market access structures in Europe.

IGES Pharma provides fully integrated market access support covering all market access processes related to the launch of products in key European markets. From strategic planning to the launch process, from data analysis to health economic and HTA applications, from KOL management to listing decisions and P&R negotiations, IGES puts its experience at the service of its clients. This allows them to focus on key decisions and shaping business strategy.

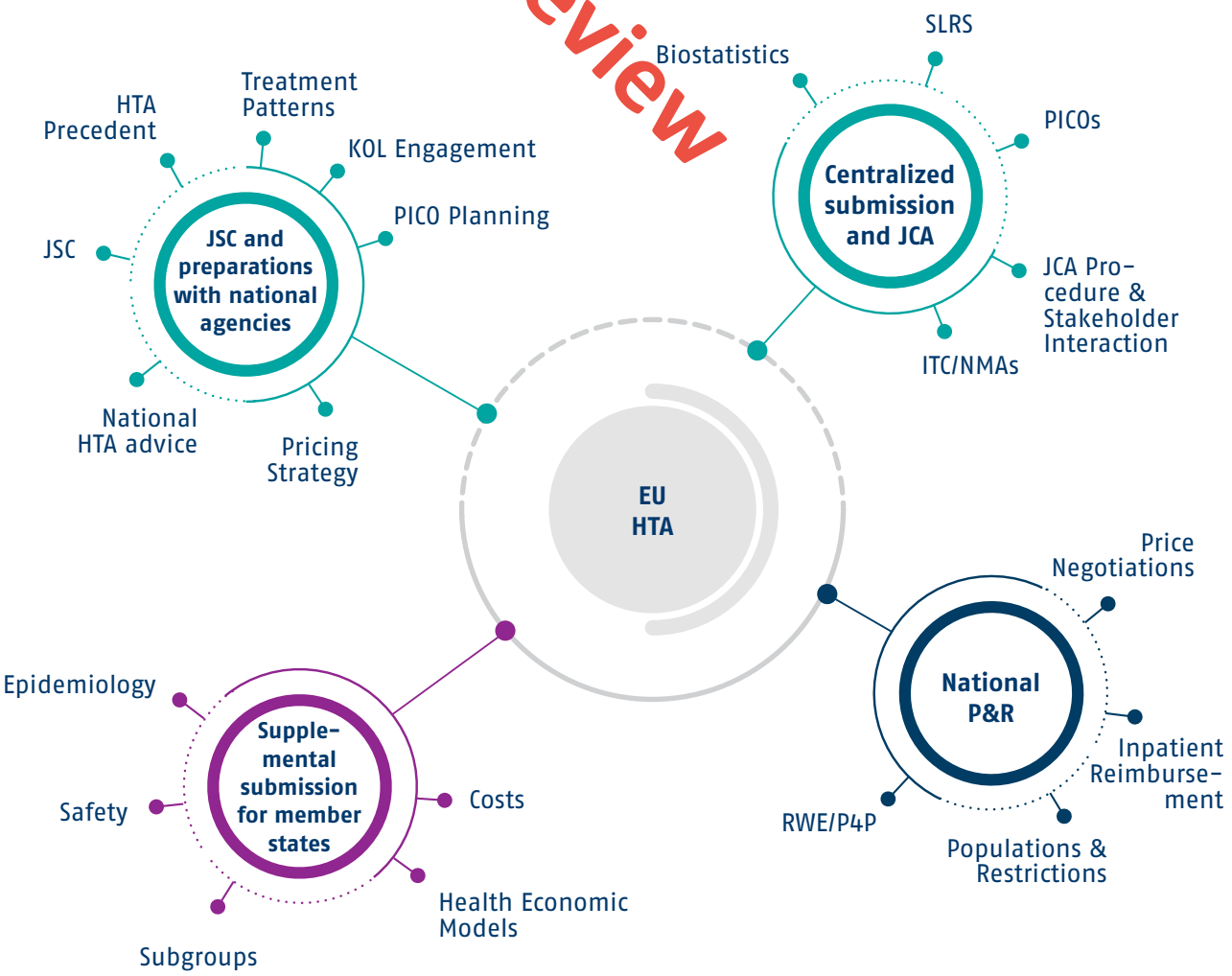


Evidence Generation

Real-world evidence is becoming increasingly important for European HTA agencies. This applies in particular to medicinal products for which there is not yet sufficient data, or which are being developed for rare indications. In these cases, the competent HTA authorities may request additional data.

The collection of RWE can be done as a proactive measure to enrich your HTA application or as a reactive measure following a request from the local HTA agency. In both cases, IGES can support you in the collection of RWE: from study design, recruitment of study sites, data collection, biostatistical analysis to presentation of results and submission to the HTA process. With our in-house CRO and biostatistics teams, we can support you all along the way.

Due to its unique positioning as a trusted partner for all key stakeholders in healthcare, IGES also supports its clients with strategic advice and communication support in the area of evidence generation. Some innovations, more than others, require early dialogue with payers, providers and policy makers. IGES has many years of experience in developing data for the European HTA process and collecting data to promote patient access to highly innovative medicines.



EU HTA (Joint Clinical Assessment)

Navigating the European Union's harmonized HTA framework, which has been gradually introduced since January 2025, is a major challenge for all stakeholders. While there is a centralized clinical assessment, EU Member States remain responsible for defining populations, comparator groups and outcomes (PICOs), as well as for all pricing and reimbursement decisions. The resulting procedure is a hybrid system that requires perfectly coordinated national and central activities. IGES has accompanied the EU legislative process for the harmonized procedure from the very beginning. IGES therefore has in-depth knowledge and an EU-wide network to provide its clients with comprehensive and targeted support in making the best possible use of the harmonized procedure for new drug launches in the EU.

IGES GmbH
Friedrichstraße 180
10117 Berlin
Germany

P: +49-30-230 809-0
pharma@iges.com

pharma.iges.com

Bestell-Nr.: 357-250909-1-REI_EU