FORUM

Market Access: Basic Concepts and Processes

White paper on the Most Important Legal Foundations and Processes

Leila Dörfler, Dr Henriette Wolf-Klein

Dear Reader

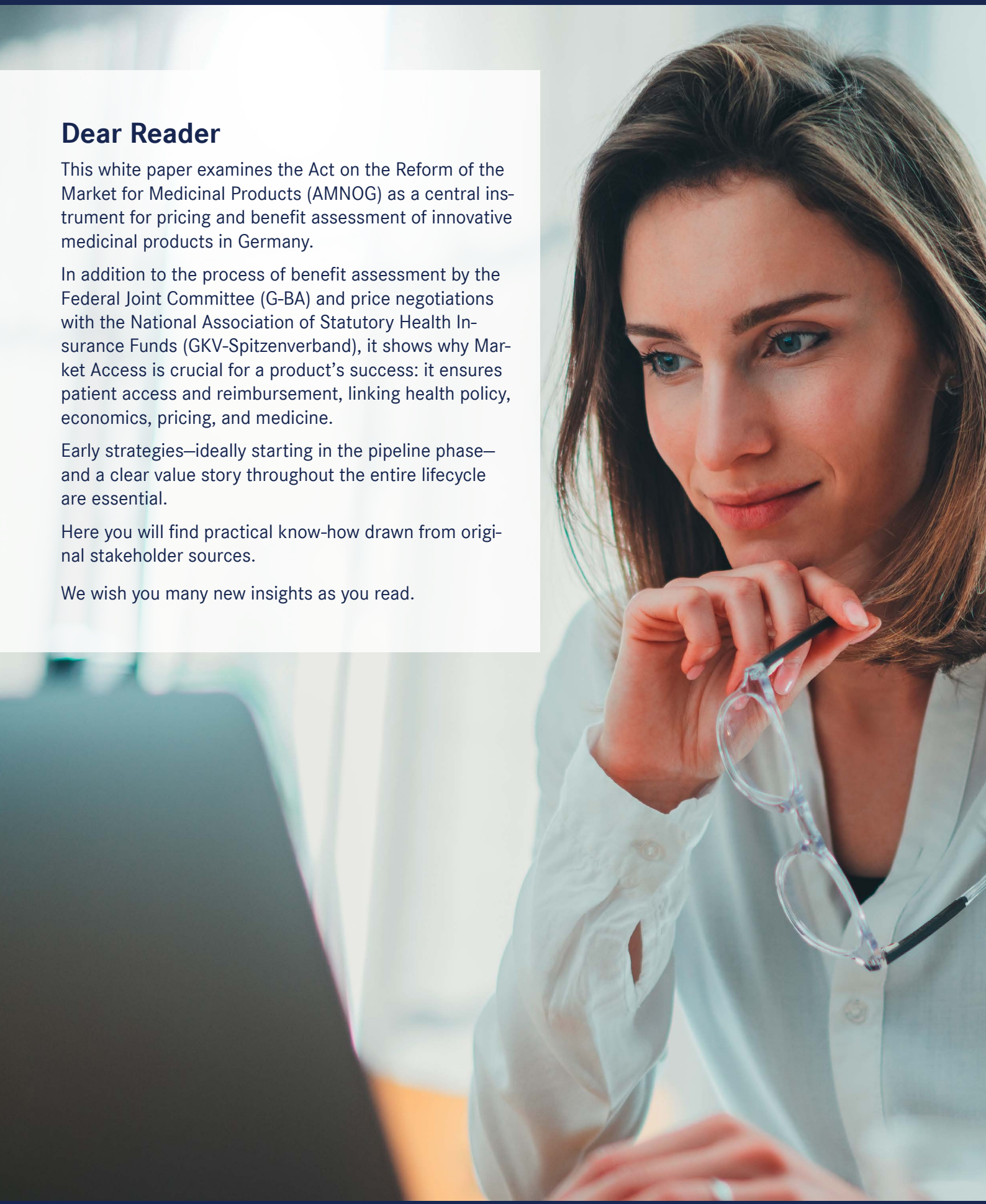
This white paper examines the Act on the Reform of the Market for Medicinal Products (AMNOG) as a central instrument for pricing and benefit assessment of innovative medicinal products in Germany.

In addition to the process of benefit assessment by the Federal Joint Committee (G-BA) and price negotiations with the National Association of Statutory Health Insurance Funds (GKV-Spitzenverband), it shows why Market Access is crucial for a product's success: it ensures patient access and reimbursement, linking health policy, economics, pricing, and medicine.

Early strategies–ideally starting in the pipeline phase–and a clear value story throughout the entire lifecycle are essential.

Here you will find practical know-how drawn from original stakeholder sources.

We wish you many new insights as you read.



ChatGPT and NotebookLM were used as supporting tools in the creation of this white paper.

Introduction to Market Access

The field of Market Access is crucial to the success of a medicinal product because it secures patient access and reimbursement by health insurers. It operates at the interface of health policy, health economics, pricing, and medicine. Healthcare Management is broader and collaborates with departments such as medical affairs, marketing/sales, regulatory affairs, and pricing at national and global levels to optimize communication and process management.

A Market Access strategy must be developed early, ideally already in the pipeline phase, to accompany the entire product lifecycle—from development to launch to patent expiry.

The "value story" plays a central role throughout the lifecycle. It defines the added value for patients by answering which patient groups benefit, which medicinal product serves as the comparator, and which endpoints are relevant. Developing a consistent Market Access strategy requires cross-functional alignment between medical affairs, regulatory affairs, and Market Access.

1. Market Access Basic Concepts

- **Healthcare Management:** A comprehensive strategic approach in healthcare that integrates, among other functions, medical affairs, marketing/sales, regulatory affairs, pricing, and Market Access.
- **Market Access:** The process that ensures a medicinal product's market entry and its reimbursement by health insurers.
- **Value Story:** The presentation of a medicinal product's medical and economic value, dynamically adaptable to new evidence.
- **Health Technology Assessment (HTA):** An assessment of the medical, social, ethical, and economic aspects of health technologies. In Germany, closely linked to the early benefit assessment under AMNOG.
- **Appropriate comparator therapy (zVT/ACT):** The standard or established therapy against which a new medicinal product is compared in the early benefit assessment to determine its additional benefit.
- Additional benefit: The therapeutic advantage of a new medicinal product compared with the zVT. Categories: major, considerable, minor, not quantifiable, additional benefit not proven.
- **Reimbursement price:** The price agreed between the GKV-Spitzenverband (National Association of Statutory Health Insurance Funds / GKV-SV) and the pharmaceutical company—or set by an arbitration board—based on the demonstrated additional benefit. This price applies retroactively from the seventh month after market entry and serves as a maximum price for hospitals.
- **Reference price:** A maximum amount up to which health insurers cover the cost of a medicinal product. Reference prices are set for groups with identical or comparable active ingredients or therapeutically comparable effects. Medicinal products priced at least 30% below the reference price can be exempt from patient co-payments.

- **Patent protection:** Protects the technical invention (e.g., active substance) for 20 years from filing and prevents manufacture, use, and marketing by third parties.
- **Data exclusivity:** Protects the regulatory data (studies) of the original medicinal product for 8 years, plus 2 years of market exclusivity (10 years total) from first EU authorization. During data exclusivity, the authority may not rely on the originator's data to assess generic applications.
- **Rebate contracts:** Contracts between health insurers and manufacturers providing price rebates for certain medicinal products. Pharmacists must preferentially dispense rebate products.
- **Principle of economic efficiency (§ 12 SGB V):** Services must be sufficient, appropriate, and economical. If two therapies are equally suitable, the more cost-effective one should be chosen. Prices become relevant where therapies are medically equivalent.
- **Practice-specific circumstances:** Special circumstances in a medical practice (e.g., an above-average share of severely ill patients) recognized in economic efficiency reviews. Under defined conditions, above-average prescription costs may still be considered economical.

2. The Most Important Processes in Market Access

Legal Basis in the Social Code Book V (SGB V)

Statutory Health Insurance (GKV) is the central pillar of the German healthcare system, covering almost 90% of the population. It rests on three core principles:

- **Solidarity principle:** Costs are borne by the solidarity community of members and employers.
- **Principle of benefits in kind:** Insured persons receive benefits as services provided directly by healthcare providers.
- **Self-administration:** Health insurers and healthcare providers independently organize services and care within the legal framework.

SGB V is the fundamental legal source for benefits and service provision in statutory health insurance. It defines, among other things, the scope of GKV activities, from health promotion and prevention to rehabilitation.

Relevant sections for medicinal products:

- § 31 SGB V: Regulates entitlement to supply with pharmacy-only medicinal products.
- § 34 SGB V: Lists excluded medicines, remedies, and aids (e.g., lifestyle drugs, minor ailments medicines) not covered by GKV; exceptions apply, e.g., for children up to 12 years.
- § 35 SGB V: Regulates reference prices for medicines and dressings/bandages.
- § 35a SGB V: The central legal basis for assessing the benefit of medicinal products with new active substances—the core of the AMNOG process.
- § 92 SGB V: Authorizes the Federal Joint Committee (G-BA) to issue guidelines, such as the Medicinal Products Directive (AM-RL), which regulate the benefit catalog and pre-

scribing.

- § 106 SGB V: Regulates economic efficiency reviews in contracted medical care, in particular for physician-prescribed services such as medicinal products.
- § 130a SGB V: Addresses manufacturers' rebates to the GKV.
- § 130b SGB V: Regulates reimbursement price agreements between the GKV-Spitzenverband and pharmaceutical companies following the benefit assessment.
- § 130e SGB V: Introduces the combination discount for new active substances in certain combinations.

The Federal Joint Committee (G-BA) is the highest decision-making body of joint self-administration in the German healthcare system. It comprises representatives of health insurers, physicians, dentists, psychotherapists, and the hospital sector. It defines the GKV benefit catalog through guidelines. The Institute for Quality and Efficiency in Health Care (IQWiG) prepares scientific assessments of the benefit of medical interventions on behalf of the G-BA, even though AMNOG itself does not include a formal cost–benefit analysis as a fourth hurdle.

Important: Authorized prescription-only medicinal products are, in principle, reimbursable; the G-BA may decide on restrictions or exclusions.

Reimbursement of Medicinal Products in the GKV System

Reimbursement in the GKV system is multi-layered. To be reimbursable, medicinal products must be authorized by the competent authorities, confirming efficacy, safety, and a positive benefit–risk profile.

- **Prescription-only vs. non-prescription medicinal products:**
  - Prescription-only medicinal products are generally covered by the health insurer; patients pay a co-payment.
  - Non-prescription (over-the-counter) medicinal products are usually paid entirely by patients, unless for children up to 12 years or adolescents with developmental disorders up to 18 years, or if the medicinal product is considered standard therapy for certain serious diseases.

- **Co-payments and burden limit:** Patients pay 10% of the dispensing price, at least €5 and at most €10, but never more than the actual cost. To prevent undue burden, there is a burden limit of 2% of gross annual household income; for the chronically ill, 1%.
- **Exclusions and restrictions:** Non-essential or uneconomical medicinal products are not part of the GKV scope of service. The G-BA may exclude or restrict prescribing, especially for lifestyle drugs or those without particular therapeutic benefit. The G-BA's Medicinal Products Directive (AM-RL) contains detailed prescribing restrictions and exclusions.
- **Reference prices:** The GKV-Spitzenverband sets reference prices for groups of medicinal products with identical or comparable active substances. If the manufacturer's price exceeds the reference price, patients pay the difference in addition to the standard co-payment.

- **Rebate contracts:** Health insurers conclude rebate contracts with manufacturers to reduce costs. Pharmacies must preferentially dispense rebate products unless the physician excludes substitution (aut idem substitution). If patients choose a non-rebate product despite aut idem substitution, they bear the additional costs.
- **Economic efficiency review:** Since 2017, reviews have been regionalized and are conducted by joint regional offices of the Associations of Statutory Health Insurance Physicians and the health insurers. The principle of economic efficiency is decisive: where medical reasons justify a more costly therapy, it is still considered economical.

AMNOG

The Act on the Reform of the Market for Medicinal Products (AMNOG) entered into force on 1 January 2011. Its aims are to provide patients with the best and most effective medicinal products, ensure economical pricing and prescribing, and create reliable framework conditions for innovation—balancing innovation and affordability.

The AMNOG process follows a two-step principle:

1) Early benefit assessment

- For each new medicinal product or new therapeutic indication, companies must submit a dossier to the G-BA to demonstrate the additional benefit versus the appropriate comparator therapy (zVT/ACT).
- The dossier must include information on the authorized indication, medical benefit, additional benefit, the number of patients and patient subgroups, therapy costs, and requirements for quality-assured use.
- The G-BA assesses the additional benefit within three months; it may commission IQWiG.
- Additional benefit is categorized as major, considerable, minor, not quantifiable, or additional benefit not proven—based on the certainty of evidence (proof, indication, hint).
- For orphan drugs (medicinal products for rare diseases), an additional benefit is deemed proven by law; the G-BA determines its extent. However, an obligation to submit a full dossier applies once annual sales reach €30 million.
- IQWiG's dossier assessments and G-BA's decisions are public, ensuring high transparency.
- Results appear in physician information systems (AIS) to inform prescribers and support decisions.

2) Price negotiation (reimbursement amount)

- The benefit assessment result is decisive for negotiating the reimbursement amount between the GKV-Spitzenverband and the manufacturer.
- Negotiations consider the extent of the additional benefit, the annual therapy costs of the zVT, and the patent protection and data exclusivity of the zVT.
- If no additional benefit is established, the product is assigned to a reference price group or the reimbursement price may not exceed the costs of the zVT.
- If an additional benefit is established, the reimbursement price should appropriately reflect it.
- If negotiations fail, an arbitration board issues a binding decision.
- The agreed or set reimbursement amount applies retroactively from the seventh month after market entry.
- Extension to the hospital sector: Since 2017, hospital-only products have also been subject to AMNOG; the reimbursement price serves as a maximum price for hospitals.

Recent developments and changes

- GKV-FinStG 2022 introduced statutory pricing guardrails. For new medicinal products with no or only minor additional benefit, the permissible range for the reimbursement price is legally constrained.
- Medical Research Act (MFG): Since January 2025, manufacturers can agree on a confidential reimbursement price if research activity in Germany is demonstrated; this entails an additional 9% discount on the negotiated price.
- Combination discount (§ 130e SGB V): A 20% discount for new active substances used in combinations designated by the G-BA, with exceptions for medicinal products with considerable or major additional benefit.
- EU HTA: From 2025, a harmonized European process for the scientific evidence review of clinical study data for centrally authorized medicinal products will precede national processes. The clinical assessment (additional benefit) takes place at EU level; economic evaluation and price negotiation remain national. The first product groups affected are oncology medicines and ATMPs, with more to follow.

Cooperation with Health Insurers

Cooperation between pharmaceutical companies and health insurers is becoming more important given the increasing complexity of healthcare. Cooperation can take place nationally or regionally.

<u>Goals and opportunities</u>

- **Prevention:** Early disease detection and patient education (e.g., vaccination campaigns or diabetes management programs) can prevent illness and reduce treatment costs.
- **Data and evidence:** Health insurers have valuable data on disease trajectories and cost structures that can be used to evaluate the effectiveness and efficiency of new therapies.
- **Care management:** Health insurers can steer care via selective contracts and pharmaceutical agreements.

Challenges

- **Conflicts of interest:** Pharmaceutical companies are profit-oriented, while health insurers are responsible for care with cost control.
- **Data protection:** Strict legal requirements for using health data must be observed.
- **Transparency and competition law:** Cooperation must not create the impression of preferential treatment for specific products.

Innovative contracting models

- **Risk-sharing / outcome-based:** Refunds depending on the therapeutic success.
- **Cost-sharing:** Shared costs per patient.
- **Capitation:** Lump-sum remuneration per patient for a defined period rather than per service.
- **Pay for performance:** Remuneration upon achieving defined quality targets.
- **Shared savings:** Savings are shared between partners.
- **Integrated care (IV contracts):** Interdisciplinary care concepts.

Selective contracts are relevant for specific projects but are not a standard instrument in classical pharmaceutical Market Access.

References (accessed 29 Aug 2025 – mostly in German)

https://www.bundesgesundheitsministerium.de/zuzahlung-und-erstattung-arzneimittel.html
https://www.pharma-relations.de/themen/branche/koop-pharma-krankenkassen~n3537
https://www.gkv-spitzenverband.de/gkv_spitzenverband/presse/pressemitteilungen_und_statements/pressemitteilung_1851264.jsp
https://www.gesetze-im-internet.de/sgb_5/BJNR024820988.html
https://www.bundesgesundheitsministerium.de/themen/krankenversicherung/grundprinzipien/aufgaben-und-organisation-der-gkv.html
https://www.vfa.de/de/gesundheit-versorgung/gesundheitspolitik/amnog-schnell-erklaert.html
https://www.iqwig.de/presse/im-fokus/neue-arzneimittel-zulassung-nutzenbewertung-erstattung/3-das-amnog-verfahren-mehr-als-nur-kostenkontrolle/
https://www.g-ba.de/themen/arzneimittel/arzneimittel-richtlinie-anlagen/nutzenbewertung-35a/
https://www.pharmadeutschland.de/unsere-themen/preise-und-regularien/das-amnog-verfahren/
https://www.bundesgesundheitsministerium.de/service/publikationen/details/die-spreu-vom-weizen-trennen-das-arzneimittelmarktneuordnungsgesetz-amnog
https://www.gkv-spitzenverband.de/gkv_spitzenverband/presse/fokus/amnog_verhandlungen/s_thema_amnog_verhandlungen.jsp
https://www.dkgev.de/themen/versorgung-struktur/arzneimittel/fruehe-nutzenbewertung-von-arzneimitteln/

Find suitable training courses here:

Seminars on Health Policy & Market Access

Continue your professional development in Market Access, Health Policy, and Healthcare Management. This includes topics such as HTA and AMNOG, as well as the requirements for rebate contracts, cooperation with health insurance funds, and healthcare management. We guarantee high-quality professional training for your success – our ISO 9001 and 21001 certifications underline this commitment.
Learn more now.

e-Learning – Click and learn

The FORUM Institut offers a flexible form of training with quality e-learning courses. You decide for yourself when and where to learn.
Test free now.

In-house seminars – Tailored solutions

All our seminars can also be offered as in-house training.
Request your individual offer now.

FORUM · Institut für Management GmbH · Vangerowstraße 18 · 69115 Heidelberg · Germany
Phone: +49 6221 500-500 · Fax: +49 6221 500-555 · www.forum-institut.com