vfa. Die forschenden Pharma-Unternehmen
Research-Based Pharmaceutical Companies

AMNOG 2025 – Current Areas of Action

AMNOG is a hallmark of the German pharmaceutical sector. However, medical progress is advancing rapidly and action is needed today to ensure that patients in Germany continue to enjoy rapid access to medicines, including advanced therapies. At the same time, the new European health technology assessment process due to launch in 2025 needs to be integrated effectively into the German regulatory framework. This paper shows what effective action for long-term stabilization and modernization might look like, and why recent legislation has thrown the existing system into disarray.

"AMNOG": a hallmark

AMNOG ("Arzneimittelmarktneuordnungsgesetz" or Pharmaceutical Market Reorganization Act), is the procedure for benefit-based pricing introduced in Germany in 2011. Since then, all drugs with new active ingredients have undergone the AMNOG procedure involving benefit assessment and price negotiations.

Pharmaceutical manufacturers negotiate reimbursement amounts for new drugs with the National Association of Statutory Health Insurance Funds (GKV-Spitzenverband) based on a rigorous assessment of additional benefit by the Federal Joint Committee (G-BA). The guiding principle up to now has been this: Statutory health insurers should only pay more if the G-BA has determined that the new drug is an improvement on the current standard treatment. If that is not the case, the price of the comparator therapy determined by the G-BA was used to cap the price of the new drug. In the rare cases where the negotiating parties could not agree on a reimbursement amount, the AMNOG Arbitration Board determined it.

For over twelve years now, AMNOG has delivered what the policymakers expected of it: It ensures billions in savings for the solidarity-based community of insured persons while providing incentives for rapid market entry and high availability of innovative drugs for patients. Up until recently, Germany led in this area in Europe.

Current situation

Gene and cell therapies, drugs targeting small, specific patient populations, and mRNA technology represent a new era of precision medicine where traditional pathways of evidence generation are reaching their limits. This presents Germany with the challenge of adapting the AMNOG framework for benefit assessment and price negotiations to keep pace with the rapid pace of scientific progress in medicine. These novel therapies need a more open and flexible AMNOG – the current system's learning curve is simply too flat to cope.

In addition, AMNOG needs adjustment ahead of the implementation of the European Health Technology Assessment (HTA) Regulation. Starting from 2025, new medicines will undergo a European clinical evaluation process in a multi-stage model. The processes and methods that apply in Germany need to be made "Europe-ready" accordingly. The processes are intended to work hand-in-hand, avoiding any additional effort or redundancy that might delay market access.

Recent legislation

The pharmaceutical industry and many experts are warning about the medium- and long-term consequences of recent legislation. The GKV Financial Stabilization Act (GKV-FinStG) radically changed the pricing rules for new drugs. The legislature constructed a rigid framework of requirements for price negotiations, devaluing the additional benefit decision of the G-BA and undermining the principle of benefit-based pricing. A drug that is superior to the standard of care may no longer necessarily be awarded a higher price. Moreover, flat-rate price discounts were added on top for combination therapies.

These structural interventions have put the AMNOG process in a precarious position. They are affecting the availability of new therapies in Germany just a few months after coming into effect and are contrary to a sustainable location policy for research-based pharmaceutical companies.

Areas of action

vfa is presenting these proposals in the hope of making a constructive contribution to the current reform debate and lending strong support to AMNOG's necessary modernization. The following proposals are presented for discussion:[1]

1. Strengthening the "AMNOG principle"

The core principle of benefit-based pricing for innovative drugs has always been that a price above the previous standard therapy is justified where the new treatment method represents an improvement. This logic was recently undermined by the legislator with new guidelines for reimbursement amounts (so-called "guardrails"). Important patient-relevant therapeutic improvements may no longer be recognized in price negotiations between the manufacturer and the GKV-Spitzenverband in many cases. In many therapeutic areas, including chronic diseases such as type 2 diabetes and mental health issues, the "guardrails" can have a counterproductive effect. The new negotiation framework deprives negotiating parties and the arbitration board of the previous ability to consider the special features of specific situations or take limitations of the AMNOG benefit assessment methodology into account to set prices or keep drugs available on the market as essential alternative treatment options.

The introduced combination discount also undermines this principle, putting immense price pressure on a host of innovative drugs. Although the use and cost of free combinations of new drugs is already taken into account in price negotiations, an additional blanket discount of 20 percent is now supposed to be paid to health insurers. A political course correction is urgently needed here also.

vfa suggests strengthening the negotiation principle of AMNOG. Negotiating parties need the necessary flexibility to recognize therapeutic improvements and to take the respective market situation into account. Elements that are alien to the system, such as rigid "guardrails" and additional blanket discounts, restrict this flexibility and need to be taken out of the legal framework.

2. Recognition of special treatment situations

New therapies are becoming increasingly targeted in nature. Scientific progress thus poses a challenge for benefit assessment as the group of patients treatable by a particular therapy becomes smaller. Classic randomized controlled trials (RCTs) designed to study larger patient populations, which still serve as the gold standard, are practically impossible for some new treatment approaches. Research is then focused on other study concepts, and regulatory authorities have been adapting to this development for years. The focus is on a situational, case-specific evaluation of what constitutes appropriate study designs. In AMNOG benefit assessment, however, only classic RCTs are routinely accepted as the basis for assessment. Little consideration is given to the specifics of treatment situations. There is a risk of an increasing disconnect between healthcare

[1] The proposals are presented in more detail in a vfa background paper prepared with the facilitation of Prof. Jürgen Wasem, University of Duisburg-Essen, and Timm Volmer, Smartstep Consulting.

provision in Germany and scientific progress in medicine. This is not an acceptable situation.

vfa suggests making the AMNOG evaluation criteria more adaptable to medical progress. More effective consideration should be given to the special features of specific treatment settings in order to assess study designs and results. This enables case-specific assessment and consideration of additional benefit. Especially in special treatment situations, categorical rejection of evidence is unacceptable. Instead, joint agreement should be reached on how the available evidence can best be utilized for benefit assessment.

3. Scope for new contract models

Performance-based reimbursement models are currently difficult to implement in the context of price negotiations with the GKV-Spitzenverband. In practice, such models have not played a major role in Germany to date. In contrast to rigid requirements, flexible solutions can also lead to savings in the healthcare system without endangering access to healthcare.

vfa suggests expanding the legal framework and creating the legal foundations for the implementation of such models. In special treatment settings with justifiably limited evidence, such as potentially curative one-time therapies, contracting parties should have more leeway for compensation design than the traditional normative framework currently provided by the Social Security Code (especially section 130b SGB V). In this context, it must also be ensured that the various models are adequately reflected in the financial compensation system of the health insurance funds (Morbi-RSA).

4. Promoting access to drugs that are the sole treatment options in a therapeutic area ("therapeutic soloists")

In treatment settings with a high unmet medical need, every new therapeutic option is of great importance to patient care. This applies, for example, to the treatment of rare diseases and cancer patients after the failure of existing treatment options in specific indications.

The Federal Social Court recognized the special importance of these drugs in February 2023. For reasons of healthcare policy, the legislature has already established special provisions for orphan drugs and reserve antibiotics within AMNOG. The process of benefit assessment is simplified for them through the statutory determination of additional benefit.

vfa suggests further measures to boost access to therapeutic options in these special areas. Beyond the existing guidelines, all new therapies addressing a high unmet medical need and that have already demonstrated an improvement in the treatment situation through positive clinical trials should be granted an additional benefit rating per se. They would then be price-regulated under these initial conditions within AMNOG.

5. Priority for European health technology assessment

European HTA begins on January 12, 2025 for the first products, including advanced therapy medicinal products (ATMPs) and oncology drugs. This is intended to improve access to innovative therapies in Europe, reduce bureaucratic burden for companies and national HTA authorities, and boost the quality of clinical evaluation across the EU. Efficient collaboration at the European level should also enhance and sustain Europe as a successful biotechnology hub. To achieve these goals, clear priority rules for the results of European HTA are necessary in AMNOG.

vfa suggests establishing a mandatory consideration of joint European work results in the national process. This helps avoid redundancy and contradictory assessments that would necessitate additional effort and confuse patients. In addition, national processes must connect seamlessly to European groundwork without delaying rapid market access in Germany. Adequate involvement and consultation of pharmaceutical companies at the critical interface of these processes needs to be ensured through new provisions.

Conclusion

To ensure the long-term success of AMNOG, there is an urgent need to adapt individual provisions

and procedures to the new challenges. The research-based pharmaceutical companies are ready for constructive dialogue on these areas of action.

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