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

Position paper

Making AMNOG future-ready

Germany has a well-balanced regulatory framework for drug evaluation and reimbursement that gives patients access to innovative drugs faster than in other countries. In fact, Germany tops the European rankings on this score. Medicines are immediately and reliably reimbursed by health insurers in this country as soon as approved. In parallel, the new medicines undergo AMNOG benefit assessment and price negotiations.

The point is not to destabilize this established system, but to improve it with the measured input of all stakeholders. The main objectives must be to empower innovation, strengthen the focus on delivering quality health care, and improve processes.

Fast access and benefit-based pricing

AMNOG stands for the "Arzneimittelmarktneuordnungsgesetz" (German Medicinal Products Market Reorganization Act), which entered into force in January 2011. Under the AMNOG procedure, amounts of reimbursement for new, patent-protected drugs are negotiated based on an assessment of additional benefit by the Federal Joint Committee (G-BA). This means that health insurers only pay an amount equivalent to the new drug's determined additional benefit versus the existing standard of care. The system thus provides a framework for fair, benefit-based pricing for all parties.

On the one hand, the reimbursement rules provide positive incentives for rapid market access and delivery of innovative drugs to patients. On the other hand, the system addresses the interests of health insurance providers in stabilizing drug spending and keeping advanced therapeutic solutions affordable. AMNOG has now become a major force in helping to stabilize drug expenditures. In 2021 alone, AMNOG reimbursements are expected to reduce the burden on health insurance funds by €6 billion.

This regulatory framework should be maintained in principle. The price specifications, additional discounts and patient prescription restrictions being called for by healthcare payers are clearly unacceptable and would be detrimental to the goal of prioritizing care delivery to patients. Instead, AMNOG should be improved in the right and necessary places with the joint input of all stakeholders, the aim being to create a reliable framework for industry and the self-administration bodies for the next decade.

Opportunities for further development and strengthening

In the vfa's view, the main points requiring attention are the following:

Improve governance

The responsibilities for additional benefit assessment and price negotiations are not separated clearly enough at present. The National Association of Health Insurance Organizations (*GKV-Spitzenverband*) is initially involved in selecting

the appropriate comparator therapy, and hence the price anchor, and also in the benefit assessment decision through its participation in the G-BA. It then holds a monopoly in subsequent reimbursement negotiations with the pharmaceutical company. In other words, it is rule maker, referee and player in one. As a result, the scientific standards of evidence-based medicine that should guide early benefit assessment tend to be eclipsed in practice by budgetary objectives. Moreover, there should be more legislative leeway for decentralized reimbursement agreements between individual health insurance providers and pharmaceutical companies as a real alternative to negotiation with the *GKV-Spitzenverband*. Such agreements would be closer to real-world practice and could better resolve the contradiction arising from national and regional medicines control.

Follow the evidence better

The restrictive methodology for benefit assessment is still leading to non-admission of available evidence on new drugs. Just one example: studies submitted by the pharmaceutical company during the approval process are often not admitted as evidence in the subsequent benefit assessment. Even real world evidence, which is widely accepted on an international level to help close data gaps, still has no role anywhere in the AMNOG process. The new instrument of real-life data collection offers opportunities for change – but only if the tool is implemented in a workable way that involves collaborative exchange. G-BA collaboration with the regulatory authorities should be expanded across the board – especially with regard to novel study designs and fast approvals – to ensure a positive contribution to delivering patient care.

Optimize processes

AMNOG processes are now routine for the parties concerned. The formal procedure is clearly defined every step of the way from dossier submission to the price negotiations. Research-based pharmaceutical companies frequently lack the specific details they need for proper planning, however. G-BA specifications for conducting clinical trials, compiling dossiers and for the benefit assessment process itself must be reliable. This applies in particular as regards specification of the appropriate comparator therapy, which forms the basis for long-term decisions on clinical trial design by the pharmaceutical companies. The option for timely consultation with the G-BA is also crucial. In addition, the expertise of healthcare professionals should be used even more in the consultation and benefit assessment process and made transparent to the pharmaceutical companies. Another necessary step is to review whether the very extensive and recently significantly expanded G-BA dossier specifications are actually necessary to assess the benefit of the medicinal products concerned.

Keep negotiated reimbursements confidential

Germany stands quite alone in Europe and worldwide with its practice of publishing the negotiated amount of reimbursement as a list price. It means the amount of reimbursement established in Germany can be referenced in other countries, which adversely affects price negotiations in this country and promotes supply problems in Germany by encouraging parallel exporting. A rethink is required on this issue. The agreed reimbursement should be known only to the parties directly involved in the negotiations. At a minimum, the parties should be given more flexibility to keep the outcomes of negotiations confidential.

Promote innovative reimbursement models

New reimbursement models (pay-for-performance approaches, etc.) can be suitable solutions in individual cases to bring possibly life-saving therapies to patients fast while safeguarding the financial stability of health insurance providers. To achieve this, however, the AMNOG regulations would need to be implemented flexibly in order to properly address the circumstances of each case. In addition, Morbi-RSA (morbidity risk structure adjustment) modifications would be necessary to eliminate existing disincentives in the design of new reimbursement models with a payback option.

European perspective

Synergies resulting from a Europeanization of benefit assessment (introduction of an EU HTA process) should be leveraged. The presentation and evaluation of clinical evidence will take place on a European level in the future. The assessment of additional benefit by the G-BA will then be

based on this. Germany should seize this opportunity to reduce divergences in the assessment of the clinical benefit of innovative therapies in Europe without conceding national sovereignty in reimbursement issues and without compromising on rapid access to innovative therapies in Germany.

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