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

Position paper – AMNOG 2025

AMNOG needs to set the course for European HTA

European health technology assessment (HTA) of new medicines will run parallel to the approval process starting from 2025. The aim is to improve the availability of new therapies across Europe, streamline procedures and boost innovation in Europe. To achieve this, it is crucial to set the right course within AMNOG, the German benefit assessment framework. Additional national regulations are required to ensure a seamless link of European and national processes, optimal use of results, and business predictability.

Starting January 2025, European Health Technology Assessment (HTA) evaluation will commence for oncological therapeutics and advanced therapy medicinal products (ATMPs). An EU regulation governs the collaboration of member states on the clinical aspects of HTA. For Germany, it means clinical study assessments will take place at the European level, going forward. However, the assessment of the added benefit and the pricing remain, as before, a national responsibility. Member states must give due consideration to the European HTA assessment report in their decision-making but may conduct complementary clinical analyses if needed. A binding mechanism governs the one-time submission of clinical data at the EU level, which cannot be requested again and re-submitted at the national level.

The introduction of European benefit assessment aims to enhance the availability of innovative therapies in the EU, reduce the bureaucratic burden for HTA authorities and companies, and boost the quality of clinical assessment. Efficient collaboration at the European level is intended to reinforce Europe as a successful pharmaceutical hub and support the sector's competitiveness.

To achieve these goals, the right course needs to be set within the framework of AMNOG (Pharmaceutical Market Reorganization Act), the German benefit assessment system, to ensure a seamless link of European and national processes and to reduce bureaucracy. Research-based pharmaceutical companies are providing specific recommendations for action in this regard.

Priority for European assessments

To increase the efficiency and quality of future HTAs, clear priority rules are needed for the European results of benefit assessment within AMNOG. Pooling the expertise of national HTA agencies at the European level and involving the Institute for Quality and Efficiency in Health Care (IQWIG) and the Federal Joint Committee (G-BA) is the best way to ensure a maximum level of quality in the results of the European benefit assessment system. To reduce duplication at both the national and EU level and reduce bureaucratic

burden, the results of European assessment must be used comprehensively within AMNOG.

The vfa therefore proposes to establish a mandatory use and adoption of the common European assessment results in the national procedure. Adopting these results reduces duplication of effort and may help to reduce disparities in the clinical evaluation of innovative therapies in Europe. Increased efficiency supports the competitiveness of the sector.

Review of national requirements for analyses

To increase efficiency and reduce bureaucratic burden in European HTA, a review of national requirements for evaluations and analyses in AMNOG is needed. Currently, these requirements are extraordinarily extensive in breadth and depth and exceed the requirements in other European systems, carrying the risk of extensive complementary national clinical analyses on top of the European HTA assessment report. There are reasonable doubts about the necessity of some parts of these analyses for the German AMNOG process, particularly in terms of the informative value of subgroup and certain drug safety analyses [1,2].

The vfa therefore suggests reviewing the AMNOG regulations on requirements for analyses and evaluations for necessity and aligning them with European guidelines. This can help achieve a more streamlined and efficient HTA evaluation without compromising quality, contributing to the strengthening of Europe’s innovation hub.

Reinforcing national consultations

For optimal dovetailing of AMNOG with the European evaluation process, the national G-BA consultations of manufacturers must be strengthened. Manufacturers need additional consultations on complementary national clinical analyses that can be requested to supplement the European benefit assessment if needed. G-BA decides on these complementary analyses in light of the scope of the European assessment. The necessary certainty for manufacturers should be ensured through timely consultation options. Requests should be limited to necessary analyses, such as new data and results.

The vfa therefore proposes strengthening the AMNOG regulations regarding consultation on complementary national analyses to be submitted in addition to the European evaluation scope. This supports an optimal interlocking of processes, provides planning security for manufacturers, and ensures a continued national assessment of the highest quality.

Securing rapid market access

To ensure rapid access to innovative medicines, precise coordination between European and national procedural steps is essential. The timing of the availability of the European HTA report may pose a challenge regarding the previously rapid initiation of the AMNOG process following the granting of marketing authorization. The European HTA report is not approved until 30 days after marketing authorization and is only considered accepted after completion of the procedural review by the EU Commission within another 10 days. This carries the risk of a delay in market access opportunity and a corresponding gap in availability of innovations during this period. However, any delay of this nature would contradict the stated objectives of the European evaluation, hinder competition and ultimately be to the detriment of patients.

The vfa therefore proposes ring-fencing the AMNOG regulation to safeguard rapid market access once approval has been granted. This ensures that patients will continue to benefit from the earliest possible availability of innovations.

Tailored integration of the orphan drug regulation

To ensure access to drugs for the treatment of rare diseases (orphan drugs) in Germany, AMNOG and the European HTA process must be dovetailed in accordance with the existing German orphan drug regulation. This regulation contributes significantly to European efforts to accelerate the development of new therapeutic options for rare diseases and ensures the rapid availability of

these innovations in the German healthcare system.

The vfa therefore proposes strengthening the orphan drug regulation within AMNOG and stipulating that even in the context of European HTA, the additional benefit of orphan drugs is considered proven upon approval and that evidence versus a comparator in the national process need only be provided after the revenue threshold of EUR 30 million has been exceeded. With these stipulations, rapid access of patients to new orphan drugs in Germany can continue to be ensured.

Conclusion

With the start of the European HTA, AMNOG processes and methods need to be "fit for Europe." The objectives of the EU regulation to ensure the availability of innovations, reduce bureaucratic burden, and enhance HTA quality should guide actions. The interlocking of European and national processes should be implemented without delaying market access possibilities. Patients, the healthcare system and Europe as a business location can all benefit from the implementation of these recommendations for action.

References

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