vfa. Die forschenden Pharma-Unternehmen

Executive Summary of the vfa's position on the Act for the Restructuring of the Pharmaceutical Market in Statutory Health Insurance (AMNOG)

Benefit assessment and cost-benefit assessment of pharmaceuticals

From the vfa's perspective, the following key problems of the benefit assessment and the cost-benefit assessment are still not solved sufficiently:

- Ensuring the legitimation of the Federal Joint Committee

  Decisions by the Federal Joint Committee as a consequence of benefit or cost-benefit assessments have far-reaching impacts on patient health care. Therefore, the essential criteria and the methodology should be governed through a statutory regulation by the German Federal Ministry of Health. We believe that the intended elimination of the complaint procedure is inappropriate. Overall, the principle applies that effective legal protection must be ensured.

- Rights of participation and procedural transparency based on scoping

  A scoping process involving patients, expert circles and the pharmaceutical industry is supposed to be placed at the start of the procedure. This must be introduced as mandatory for all assessments. As a rule, hearings must be conducted orally and in writing. The requirement of procedural transparency and appropriate participation pursuant to Section 35 para. 2 of the German Social Code V (old) must be preserved.

- Handling of uncertainty in early assessments

  The ministerial draft bill neglects the uncertainty that exists with an assessment conducted close to marketing authorization: At the time of marketing authorization, comprehensive studies at the highest evidence level and for hard endpoints cannot be available. Therefore, for early assessments, the determination of the desired comparative therapy and the expected endpoints can only be made in accordance with the marketing authorization agency.

- Special status of orphan drugs

  Orphan drugs should be exempt from the early assessment, since a significant therapeutic benefit must be demonstrated for them

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at the time of marketing authorization (unless they are products without an alternative anyway).

Applicability of cartel law to statutory health funds

We welcome the fact that health funds will have to comprehensively comply with cartel law when concluding voluntary individual agreements with pharmaceutical companies as well as the fact that cartel authorities and civil courts will be in charge of this area in the future. However, we oppose the idea of the ministerial draft bill that cartel law is not supposed to apply to the centralized agreements concluded by pharmaceutical companies with the SHI Head Association. Therefore, the vfa demands:

- For the SHI Head Association, at least Sections 19 to 21 of the Act against Restraints of Competition (GWB) must apply to centralized agreements with pharmaceutical companies.

Deregulation

With the early assessment and the centralized negotiations of the terms of reimbursement, regulatory instruments from other countries are imported to Germany. At the same time, there is no comprehensive reduction of quantity-regulating instruments that do not exist in parallel in those countries. On the contrary, economic efficiency audits are aggravated instead of simplified. Therefore the vfa demands the

- Comprehensive elimination of quantity-regulating instruments, including the reimportation promotion clause.

Centralized negotiations with the SHI Head Association

Centralized negotiations with the SHI Head Association are tantamount to the establishment of a demand monopoly and must therefore be rejected. If centralized negotiations are to be instituted nonetheless, the following must be taken into account:

- Centralized negotiations must automatically replace manufacturer's discounts.
- Negotiations must be oriented on the value of the pharmaceutical.
- The use of European reference prices as a basis will be refused.
- No unilateral termination of agreements without notice.

No compulsory contracting

If the Federal Joint Committee does not identify an additional benefit for a pharmaceutical or if no agreement is reached with the SHI Head Association regarding a reimbursement amount, the Federal Joint Committee must exclude the pharmaceutical from reimbursement in statutory health insurance upon the request of the pharmaceutical company.

Establishment of a body of arbitration

The vfa welcomes the arrangement regarding the composition of the body of arbitration. However, the vfa poses the following requirements for the procedure:

- The decision-making fundamentals of the body of arbitration must be laid down in a master agreement between the pharmaceutical companies and the SHI Head Association.
- A European reference price may not serve as a basis for the procedure.
- Delays in decision-making by the body of arbitration may not unilaterally go at the expense of the affected pharmaceutical company.

Decentralized negotiations

The creation of a passage addressing the health care issue in Section 130c of the German Social Code V and the pharmaceutical companies' opportunity for active participation in integrated health care contracts as a full contracting partner, as created in Articles 18 and 19 of the draft bill, must be judged positively. However, the following items must be considered:

- Decentralized agreements must replace centralized ones.
- Health care agreements pursuant to Section 130c must be possible prior to the conclusion of centralized negotiations.
- The contractual partners must not be limited by centralized requirements in their contracting freedom.

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