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How do the stricter pricing regulations of the Statutory Health Insurance Financial Stabilization Act ("GKV-FinStG") affect reimbursement prices of new drugs in Germany?

Objectives

Stricter pricing regulations apply since the Statutory Health Insurance Financial Stabilization Act ("GKV-FinStG") came into force in November 2022, whereby new drugs with a patent/-data-protected appropriate comparator therapy (ACT) are particularly affected. The aim of this analysis is to explore the impact of the stricter pricing regulations on the reimbursement prices of new drugs in Germany.

Considering the first decisions of the arbitration board, which may serve as a guide for the implementation of the "GKV-FinStG", the application of the stricter pricing regulations is analyzed and resulting controversies are identified. Finally, the effect on future AMNOG procedures is discussed.

Methodology

Based on a systematic analysis of four relevant arbitral awards published until end of September 2023, the impact of the stricter pricing regulations on the derivation of the reimbursement prices is captured.

Subsequently, the findings and implications are applied to new drugs

- in indications characterized by generic and patent/data-protected as well as benefit-assessed and non-benefit-assessed products and
- for which the ACT is defined either as a basket of patent/data-protected and generic drugs with an "or" linkage or as a patient-specific therapy (e. g. therapy according to physician's choice).

Results

Arbitral award	Indication(s)	Additional benefit	ACT defined by G-BA	Learnings from the arbitral award
2023 Jan 17 – Jemperli® (dostarlimab)	• Endometrial cancer, following prior treatment with a platinum-containing regimen	• No additional benefit	• **Therapy according to physician's choice**, incl. endocrine therapy, systemic chemotherapies and best supportive care	• First-time **application of an exclusion to the "should-rule" (reimbursement price > costs of the ACT)** as dostarlimab may be a relevant therapeutic option in individual cases, treats a life-threatening disease, is mentioned in guidelines and was placed on the market early to meet an urgent medical need, the price level of the ACT is low, and conducting a trial with the ancient ACT as comparator would have been unethical.
Jan 23 – Libtayo® (cemiplimab)	• 1st line NSCLC • Basal cell carcinoma, locally advanced and metastatic	• No additional benefit	• **Patent/data-protected** pembrolizumab	• The partial reimbursement price for cemiplimab in 1st line NSCLC is formed by applying the stricter pricing regulation of **at least a 10 % discount** on the costs of the **patent/data-protected ACT pembrolizumab**, whereby the arbitration board deemed exactly 10 % discount (and not more) to be sufficient.
Apr 17 – Ponvory® (ponesimod)	• Relapsing multiple sclerosis (3 slices)	• Slice a1): minor additional benefit	• Slice a1): **basket of patent/data-protected and generic drugs with an "or" linkage,** incl. the patent/data-protected study comparator teriflunomide	• If the ACT consists of both, patent-protected and generic products with an "or" linkage, and **no additional, a non-quantifiable or a minor additional benefit** was proven, the **most economical option is decisive** for the application of the stricter regulations and the subsequent determination of the reimbursement price. • For monetization of the additional benefit in slice a1), a premium on the **costs of the most economical ACT** of the basket **(generic dimethyl fumarate)** is formed. • The resulting partial reimbursement price **exceeds** the price of the most economical patent/data-protected ACT and study comparator teriflunomide
May 5 – Zeposia® (ozanimod)	• Relapsing remitting multiple sclerosis (RRMS) (2 slices) • Ulcerative colitis (2 slices)	• Slice 1): minor additional benefit	• Slice 1): **basket of patent/data-protected and generic drugs with an "or" linkage,** incl. the non-patent-protected study comparator interferon beta-1a	• For monetization of the additional benefit in slice I), a premium on the **costs of the most economical ACT** of the basket **(generic glatiramer acetate)** is formed. • The resulting partial reimbursement price is **below** the price of the study comparator interferon beta-1a, to which the additional benefit was proven.

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- In case of **no additional benefit compared to a patent/data-protected ACT,** the stricter pricing regulation of at least a **10 % discount** on the costs of the **patent/data-protected ACT will lead to a downward price spiral** in indications where additional benefit is difficult to prove, i. e., chronic diseases with increasing burden of disease.
- Furthermore, the **application of an exclusion to the "should-rule" is not possible anymore in case of a purely patent/data-protected ACT** and therefore the circumstances of the individual case must no longer be considered when the reimbursement price is determined.

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- Depending on the **data/patent protection of the ACT and the price structure within indications** in cases with a **non-quantifiable/minor additional benefit** against the **ACT,** the stricter price regulations may lead to **unpredictable and inconsistent** monetization of additional benefit and/or derivation of reimbursement prices within/across (partially overlapping) indications.
- As a consequence, the reimbursement prices will become **increasingly detached from the results of the G-BA benefit assessment,** which contradicts the fundamental idea of **AMNOG**.

! In both scenarios, there is no **empirical evidence** so far regarding the implications of the stricter pricing regulations, **if therapy according to physician's choice/patient-specific therapy is determined as ACT.**

Conclusion

- The stricter pricing regulations of the "GKV-FinStG" lead to more challenging negotiations since they may prevent appropriate reimbursement for new drugs, which – regardless of the individual case – could not prove an additional benefit compared to a patent/data-protected ACT.
- Even if an additional benefit is proven, controversial and challenging implications (overcoming the price gap between generic and patent-protected comparators, loss of the relation to the study comparator) for the price structure within indications may arise due to monetization against the most economical ACT provided there is a minor/non-quantifiable additional benefit.
- Given this outlook, manufacturers will have less incentive to invest in innovations and to commercialize them in Germany, as the expected reimbursement prices are subject to uncertainty and drug prices tend to decrease in the long run, in contrast to the price level in the general economy.
- Hence, quality of care and security of supply of drugs may suffer due to limitation of therapeutic options.

References

- Federal Joint Committee ("Gemeinsamer Bundesausschuss [G-BA]"):
  - Benefit Assessment of dostarlimab (endometrial cancer, following prior treatment with a platinum-containing regimen); 2021
  - Benefit Assessment of cemiplimab (new therapeutic indication: non-small cell lung cancer, first-line); 2022
  - Benefit Assessment of ponesimod (relapsing multiple sclerosis); 2022
  - Benefit Assessment of ponesimod (relapsing multiple sclerosis, patient group b); 2021
  - Benefit Assessment of ozanimod (relapsing remitting multiple sclerosis); 2021
- Joint arbitration board pursuant to Sec. 130b Para. 5 German Social Code Book V
  - Arbitral award dostarlimab (Jemperli); 2023
  - Arbitral award cemiplimab (Libtayo); 2023
  - Arbitral award ponesimod (Ponvory); 2023
  - Arbitral award ozanimod (Zeposia); 2023

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