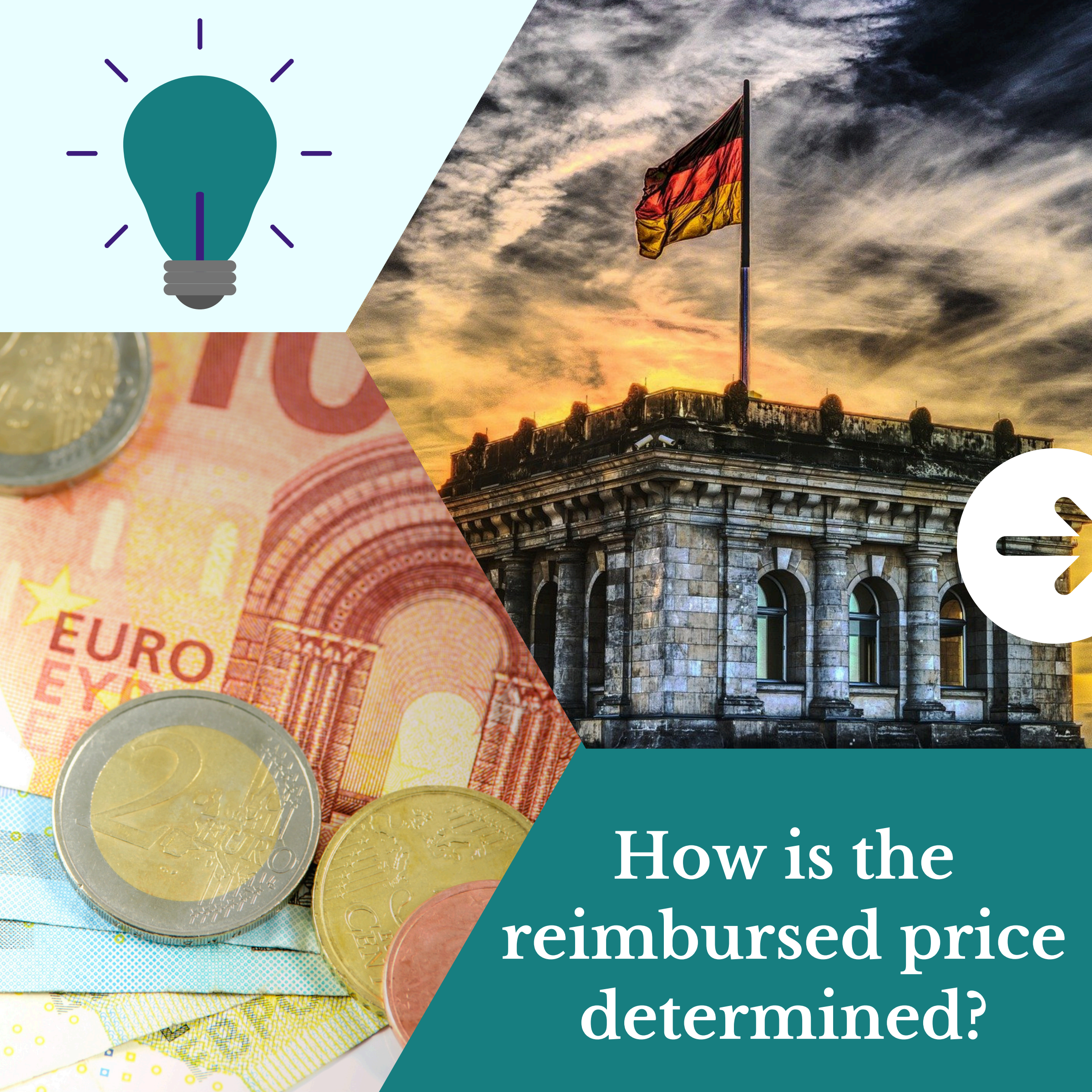




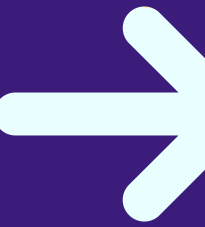
How is the
reimbursed price
determined?

At the time of launch,
pharmaceutical companies
are free to set the price for
their product.
This price is then valid for
the first 6 months.





After 6 months, price negotiations between the pharmaceutical company and the GKV-SV commence.



The pharmaceutical company and the GKV-SV are now expected to agree on a reimbursement price within 6 months. These price negotiations are confidential.



The pricing mechanism
depends on whether at least
**5% of the clinical trial
population is German.**



If $>5\%$ of trial patients are German, the price is freely negotiated based on:

- Additional benefit level
- Comparator costs
- Size of population



Otherwise, for products with a minor, not-quantifiable, or no additional benefit, the price is strictly linked to that of the comparator.



Price guardrails

for products with <5% of trial population from Germany

Additional benefit	ACT = Appropriate comparator therapy	Price rule
Major	Any	Free price negotiation
Considerable	Any	Free price negotiation
Minor or not-quantifiable	Patent-protected; previously assessed by G-BA	Annual therapy costs can't exceed those of the most economical comparator
	Patent-protected; not previously assessed by G-BA	Annual therapy costs 15% below those of ACT
	Off-patent	Free price negotiation
None	Patent-protected	Reference pricing, otherwise annual therapy costs >10% below those of ACT
	Off-patent	Reference pricing, otherwise annual therapy can't exceed those of ACT
Less / worse	Patent-protected	Reference pricing, otherwise annual therapy costs >10% below those of ACT
	Off-patent	Reference pricing, otherwise annual therapy can't exceed those of ACT

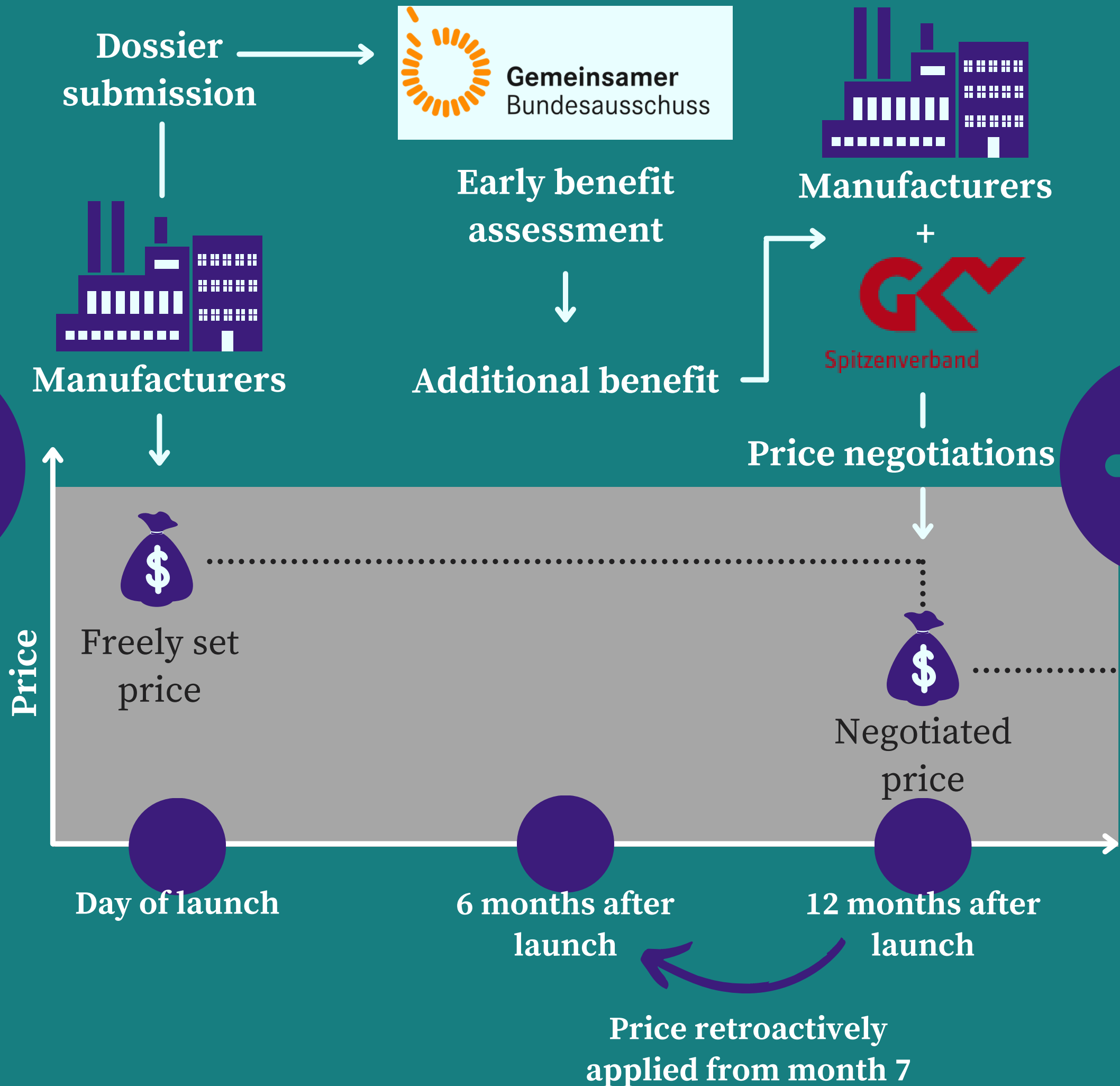
If both parties cannot agree on a price, a final decision on the price will be made by the arbitration board.



The new price will be
retroactively applied from
month 7 onwards.



Pricing in Germany



The final negotiated price is published in the Lauer Tax database (data available for a subscription fee).



Alternatively, some manufacturers can request **confidential prices** for a mandatory discount of 9% instead of publicly available list prices.

CONFIDENTIAL



The confidentiality option is available to **companies with** a drug research department and relevant projects or collaborations in (pre)clinical **research in Germany only.**



The price confidentiality framework is in force until 30 June 2028, and will be evaluated at the end of 2026.



Want to find out more?

Get In Touch



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germanmarketaccesssimplified.com

or get my **Free Guide to German HTA system**

A detailed guide to the 10 most commonly asked questions regarding early benefit assessments

