Pricing and reimbursement in Germany: At a glance

Germany has a decentralized, public–private healthcare system, with care covered primarily through statutory (87.7%) or private health insurance (10.5%)[1]

For the first six months from launch, pharmaceutical pricing is freely-set by the manufacturer and most products are reimbursed at 100%[2-7, 9*]

During this period, the Gemeinsamer Bundesausschuss (G-BA)[2,3,4] will conduct an early benefits assessment—they may also commission the Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG) to evaluate evidence submitted by the manufacturer

Based on the extent of additional benefit vs a relevant comparator, the G-BA issues recommendations on benefit and pricing:[3,4]

- If additional benefit is proven, price negotiations begin between the GKV-Spitzenverband (National Association of Statutory Health Insurance Funds); if a price is not agreed within six months, an arbitration board will make a final pricing decision
- If no additional benefit is proven, pricing is set based on an existing reference price group, if available, or so that annual treatment costs do not exceed standard treatment

As of July 2024, the Medical Research Act has introduced measures to incentivize clinical research in Germany through changes to early benefits assessment and pricing decisions:[8]

- If a manufacturer can prove local research activities and accept a 9% reduction on a product's reimbursed price, the details of product pricing will be kept confidential
- If a manufacturer can prove that at least 5% of patients in a product's trial were enrolled in Germany, the product will benefit from relaxation of current pricing guardrails

***Exceptions:** *over-the-counter drugs, lifestyle products, and products that are not considered economical where an appropriate comparator is already available*

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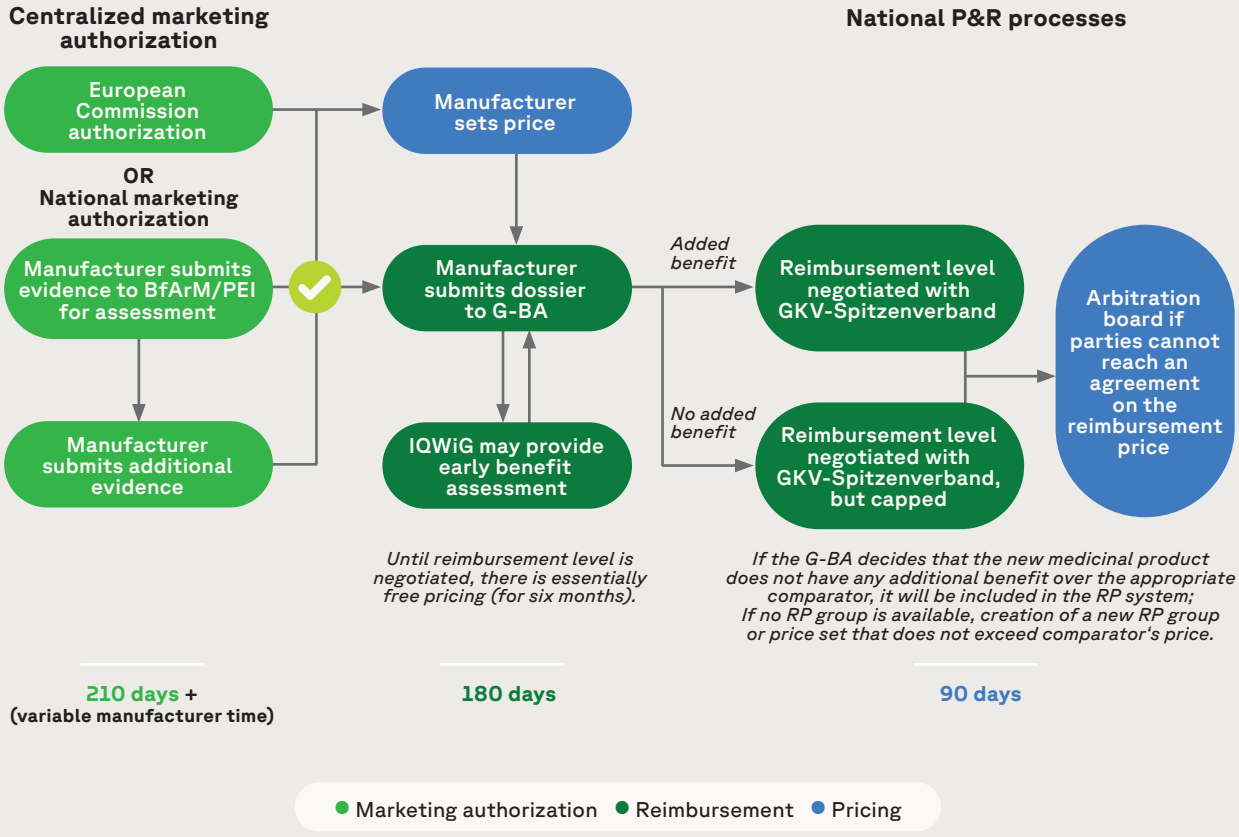
Pricing & reimbursement process[9]*

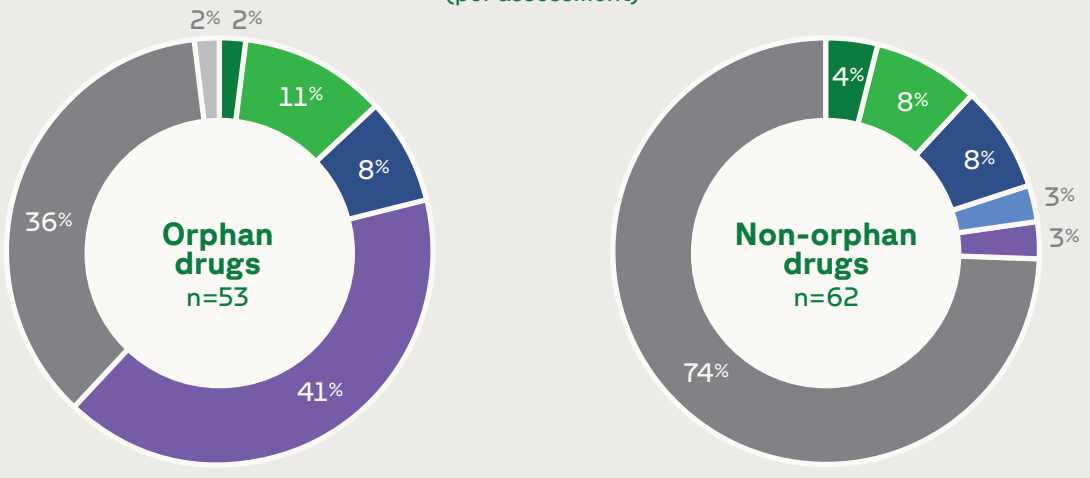


** BfArM: Federal Institute for Pharmaceutical and Medicinal Products; G-BA: Federal Joint Committee; GKV: statutory health insurance; GKV-Spitzenverband: Federal Association of GKVs; IQWiG: German Institute for Quality and Efficiency in Healthcare; PEI: Paul-Ehrlich-Institut; RP: reference pricing.*

How does clinical evidence inform pricing and reimbursement in Germany?[3,4,10]

- For early benefits assessment, G-BA and IQWiG express preference for clinical evidence **from randomized controlled trials (RCTs)** that include direct comparison vs at least one relevant comparator
  - In the absence of head-to-head RCT data, clinical evidence from non-randomized interventional, prospective observational, retrospective observational, and non-interventional studies are accepted
  - Market approval of orphan drugs implies clinical benefit and the benefit assessment does not require comparative data; if the annual sales for an orphan drug exceed €30 million a full dossier is required
- G-BA and IQWiG have strict requirements on the selection of comparators, endpoints, and patient subgroups—quality of life (QoL) data is important and patient perspective is considered
- IQWiG provides conclusions based on the results of the benefit assessment, which may differ from the findings presented by the manufacturer—the extent of added benefit is determined by three steps:
  1. Examining the probability of effect for each outcome and classifying the quality of the evidence (from low to high: hint, indication, or proof)
  2. For outcomes identified in step one as having effect, the extent of effect size (minor, considerable, major, or not quantifiable) is determined
  3. In the final step, the overall conclusion of the added benefit of all outcomes is assessed according to six categories (major, considerable, minor, non-quantifiable added benefit, no added benefit proven, and less benefit) than the appropriate comparator therapy
- The extent of added benefit established by the G-BA based on the clinical evidence determines the reimbursement price pending negotiations between the manufacturer and GKV-Spitzenverband
- Considering early benefits assessments in 2024, a minority of non-orphan drugs (26%) and a majority of orphan drugs (62%) were determined to have additional benefit compared with relevant comparators

Additional benefit by share of G-BA resolutions following early benefit assessments in 2024[11]
(per assessment)



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