



The IQWIG (Institute for Quality and Efficiency in Health Care)
 A scientific institute under the supervision of the G-BA and the German Federal Ministry of Health. On behalf of the G-BA, the IQWIG assesses existing scientific studies and their meaningfulness under medical and statistical aspects.

The dossier
 At the time of market launch, the manufacturers submit a dossier to prove an additional benefit.

Before the G-BA
 Hearing of the manufacturer and experts: decision on the additional benefit

Review of the dossier by the IQWIG and the G-BA within three months

No dossier = no additional benefit
 If possible, a reference price is set.

Opt-out
 The negotiations are prematurely terminated, if the manufacturer decides within 4 weeks not to offer his pharmaceutical in Germany.

Reimbursement amount negotiations until the 12th month

Negotiation with the SHI Head Association
 about the reimbursement amount. Parameters include: Decision of the G-BA on the additional benefit, price of comparable pharmaceuticals, European prices.

No agreement
 Upon application, the arbitration board made up of neutral third parties determines the reimbursement amount.

Agreement
 An additional benefit has been recognized. SHI and the manufacturer agree on a reimbursement amount.

Arbitration verdict by the 15th month

Doctors can prescribe the pharmaceuticals without having to fear recourse claims (practice speciality).

Manufacturer accepts the arbitration verdict
 The discount determined by the arbitration board becomes effective retroactively from the 12th month.

Manufacturer does not accept the arbitration verdict. He can withdraw from the German pharmaceutical market or file a legal complaint about the arbitration verdict.

New active ingredient

New active ingredient

Reference price

Reimbursement

Reimbursement

IQWIG

G-BA

SHI

Arbitration board

Doctor

Doctor