**Reference price**

New active ingredient

Hearing of the manufacturer and experts;

decision on the additional benefit

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.

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.

IQWiG

SHI

Arbitration board

Doctor

No dossier = no additional benefit

If possible, a reference price is set.

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

Hearing and decision between the 4th and 6th month

Reimbursement amount negotiations until the 12th month

Arbitration verdict by the 15th month

Opt-out

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

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

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

Manufacturer accepts the arbitration verdict

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

Agreement

An additional benefit has been recognized.

SHI and the manufacturer agree on a reimbursement amount.

The dossier

Before the G-BA

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

Review of the dossier by the IQWiG and the G-BA