



**Benefit Assessment
in Germany and the
European Perspective**

Evidence in the pharmaceutical policy

Prerequisites:

- 1. Patients must be protected from unnecessary harm.*
- 2. Society must be protected from unnecessary costs.*

Self Administration of Health Care in Germany

Ministry of Health

Legal supervision

**Federal Joint
Committee**

Patients, Physicians, Sickness
Insurance Funds

Decision making

<http://www.g-ba.de>

**Institute for Quality
and Efficiency in
Health Care**

**Production of evidence
based information**

<http://www.iqwig.de>

Germany and International Perspektive

In Germany, after approval by the EMEA all drugs are immediately reimbursed by the statutory health care insurance.

Prices are set by the industry only.

GBA-Decisions

- **No restrictions**
- **Treatment information**
- **Reference prices for groups-
maximum limits of coverage**
- **No coverage by the statutory
sickness funds**
- **Coverage only in clinical trials**

Assessment of harms and benefits

Patient-oriented trial outcomes (benefit and harm):

- **Life expectancy (mortality)**
- **Complaints and complications (morbidity)**
- **Health-related quality of life**
- **Intervention-related burden**
- **Patient satisfaction**

International method of benefit assessment

**A fair comparison
of alternatives in
prospective
controlled trials.**

Reasons for bias in “for-profit” trials

- **Design bias**
- **Data suppression**
- **Interpretation bias**
- **Differential data quality**
- **Suppression of publication**

IQWiG Recommendations

1. There is prove of benefit.

Positive Evidence

2. There is prove of the lack of benefit.

Negative Evidence

3. There is no prove of benefit.

Insufficient Evidence

IQWiG Recommendations

1. There is prove of benefit.

Do it!

2. There is prove of the lack of benefit.

Don't do it!

3. There is no prove of benefit.

Investigate it!

Evidence in the pharmaceutical policy

IQWiG resume after two years of work:

It is very difficult to protect the public and the individual patient from the threats to health and to the health-budget by the wide use of drugs with an unknown benefit - harm relation.