



Gemeinsamer
Bundesausschuss

Assessment of benefit

Implementation of medical innovations in Germany

Meeting

College voor zorgverzekeringen (CVZ) and
Gemeinsamer Bundesausschuss (G-BA)
Amsterdam, January 26, 2007

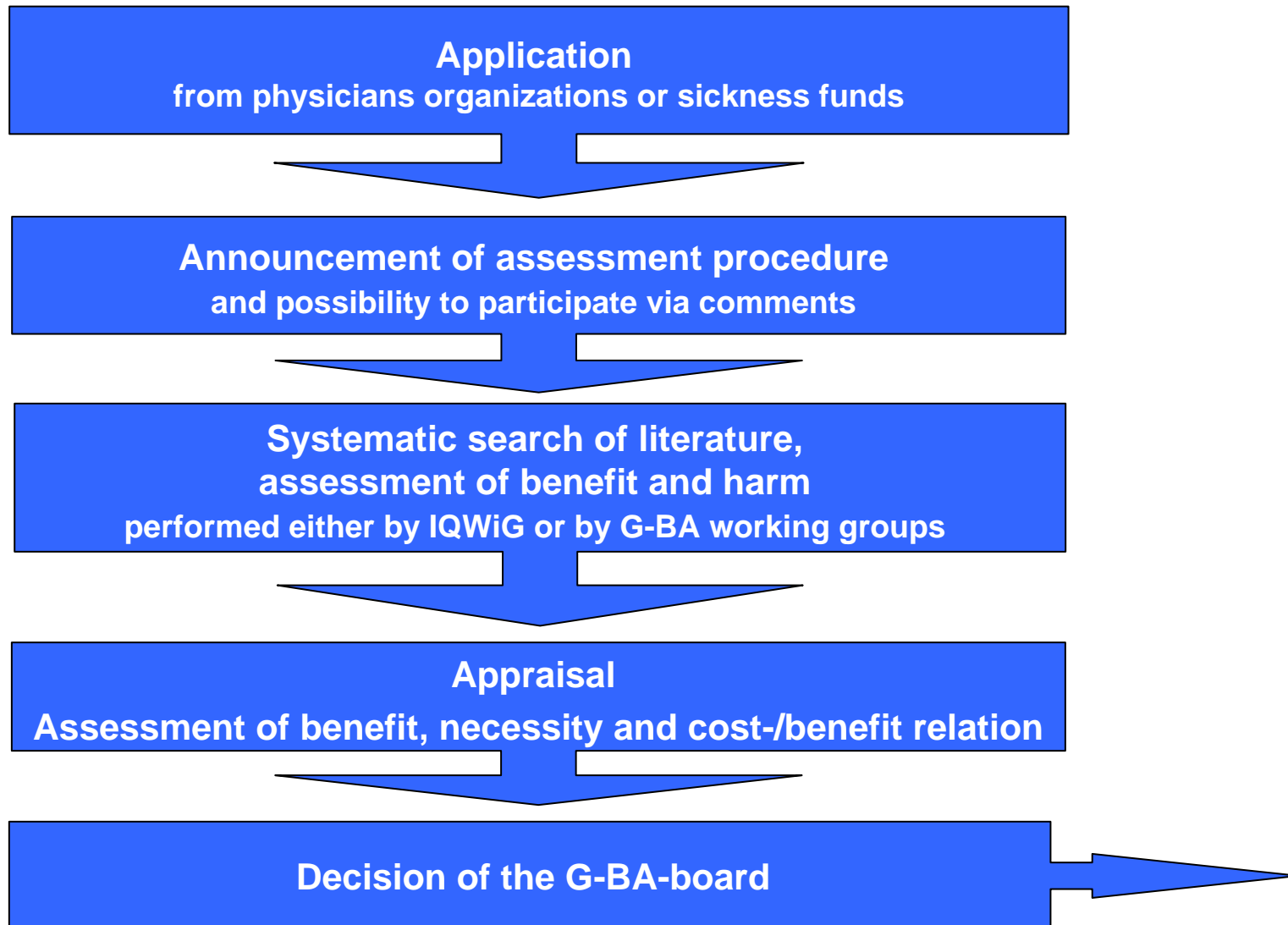
Dr. Dorothea Bronner, Federal Joint Committee (G-BA)

Principles for implementation or reimbursement of new methods (medical treatments) in the statutory health insurance (SHI) care:

Out-patient care: positive evidence based assessment as a condition to implement a new method for diagnosis or treatment:
„Methods are not reimbursed by SHI, as long as the G-BA has not yet decided about a positive benefit of the treatment“
(„Erlaubnisvorbehalt“)

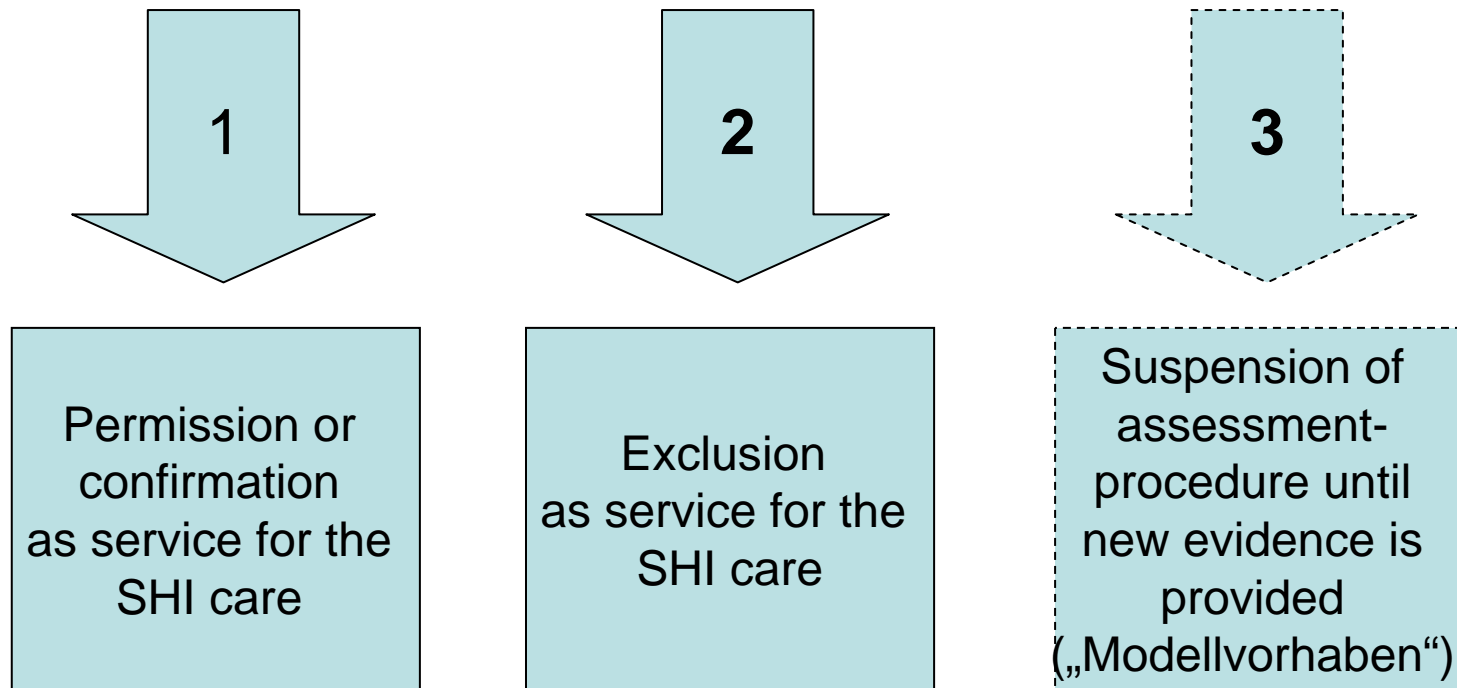
In-patient care: „negative“ evidence based assessment as a condition to exclude (new) methods
„Methods are reimbursed by SHI, as long as the G-BA has not yet decided about the „negative“ benefit of the treatment“
(„Verbotsvorbehalt“)

Procedure of benefit assessment

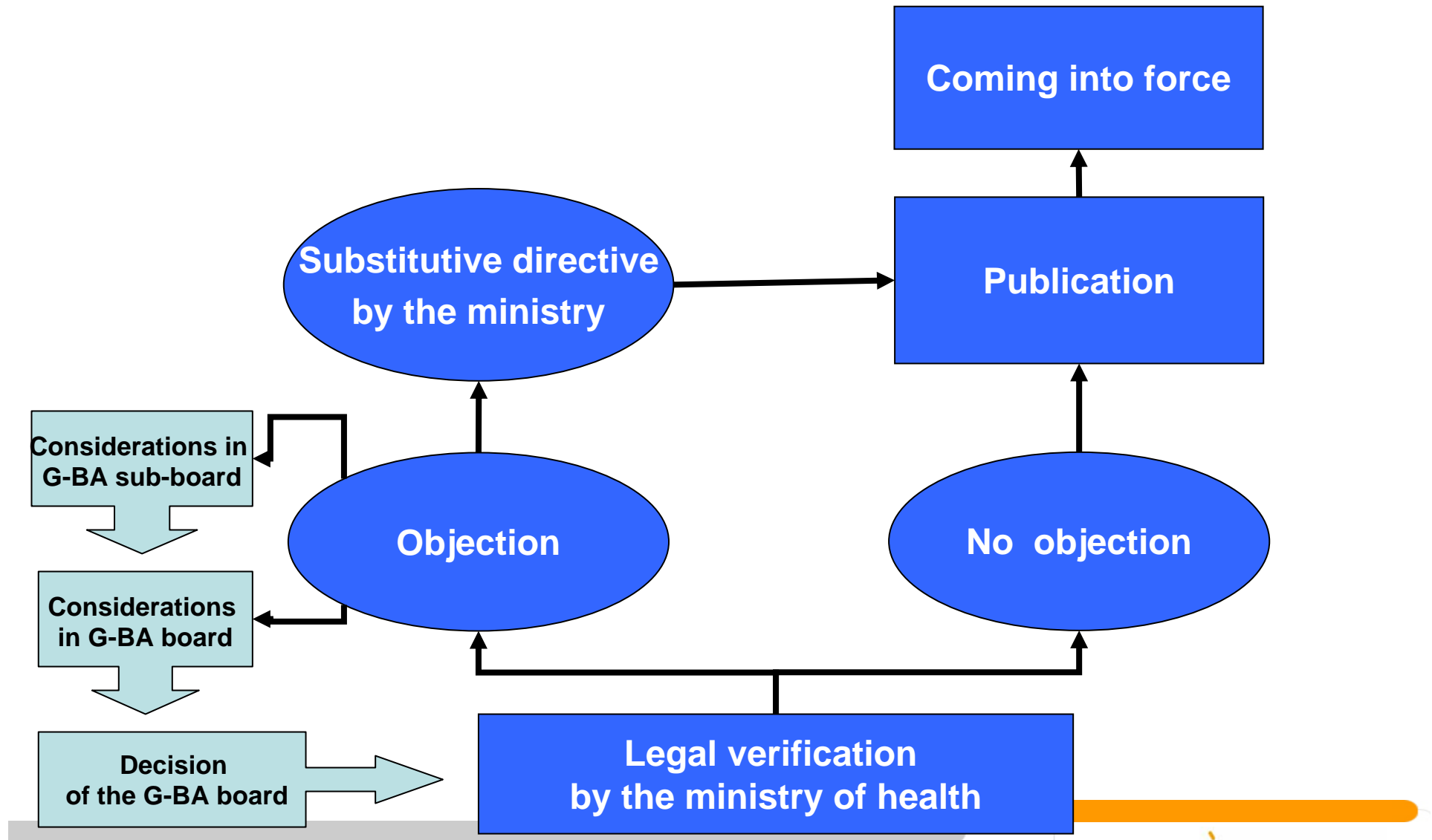


Decisions of G-BA

Possible Conclusions after Benefit-assessment



Implementation of G-BA Directives



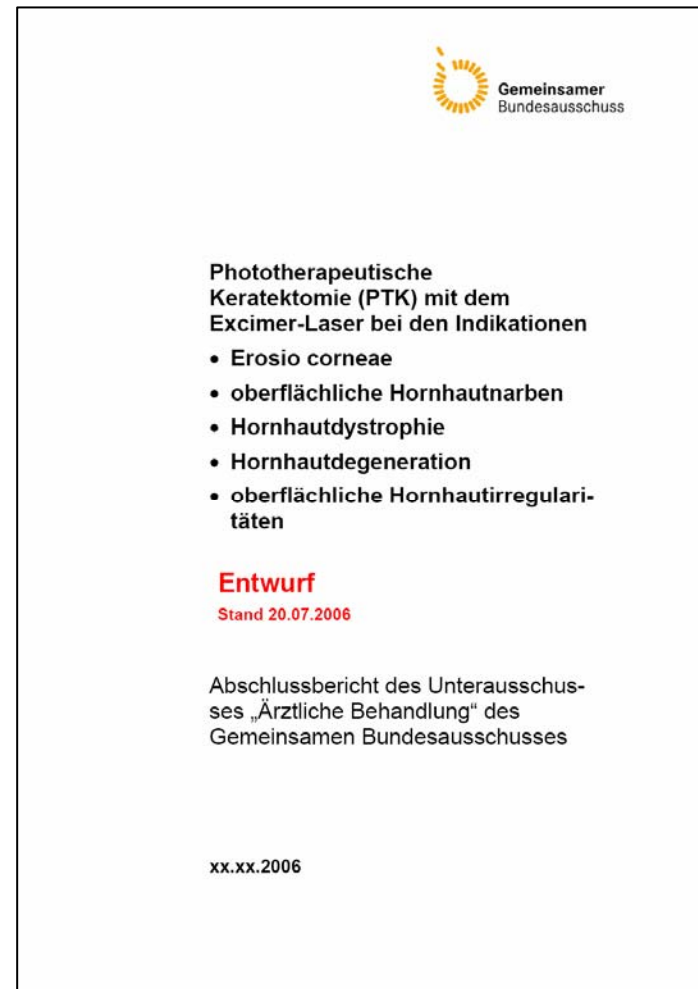
Challenges in implementation innovations

- (1) Procedure and decision about benefit assessments take a (too) long time. The implementation of innovations might be observed as delayed in some cases.
- (2) In some cases the benefit assessment is not started at all, because no formal application is initiated.
- (3) Many factors and aspects have to be reviewed and considered in addition to benefit assessment for the final decision. Each case has its own characteristics and there is no international consensus or standardized methodology so far available.

Example – „Phototherapeutische Keratektomie (PTK)“

Result of assessment:

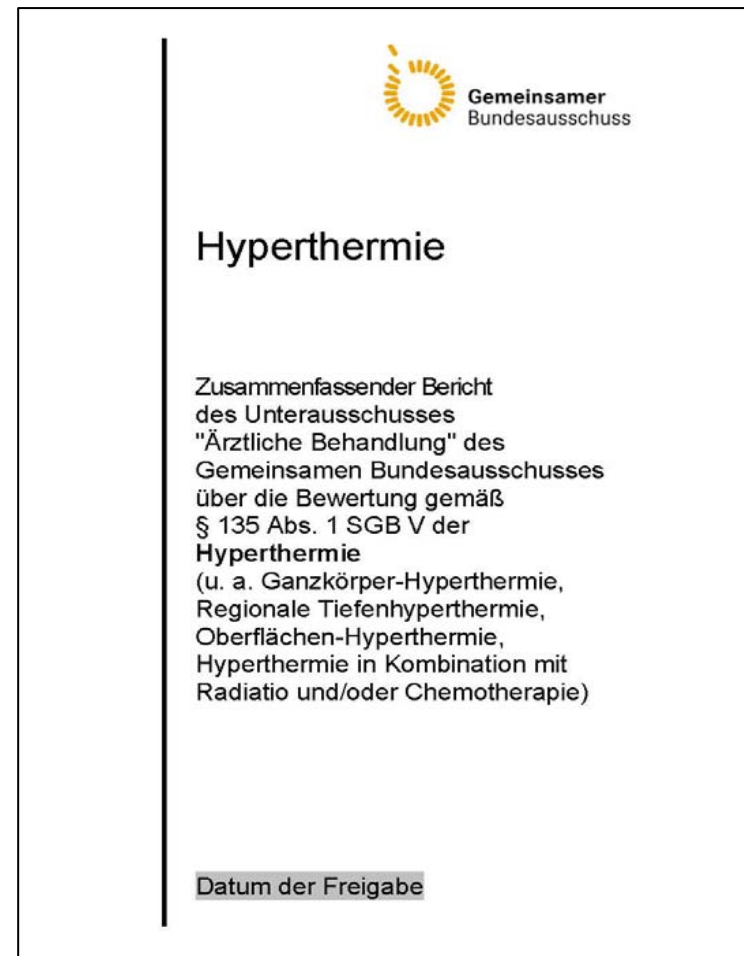
- Many indications had to be screened
 - Assessment procedure needed one year
 - Final report includes 367 pages and 59 analyzed references
- ➔ „Permission“ of the PTK for most of the screened indications in out-patient-care



Example – „Hyperthermie“

Result of assessment:

- Literature search for 20 oncologic indications
 - Assessment procedure needed two years
 - Final report includes 875 pages with 1252 analyzed references
- ➔ „Exclusion“ of the
“Hyperthermie” for all of
the screened indications in
out-patient-care



Cases with no SHI-reimbursement in out-patient-care

Just upcoming, very new method,
with only very few scientific
evidence

Rare Disease, where low or now
evidence is provided, due to
difficulties to evaluate procedures

Assessment of innovations

Method is already implemented
(for example in hospital-care), but
assessment is not initiated by the
necessary formal application

Method has been assessed by
the G-BA with a negative benefit
result and was excluded from
SHI reimbursement

Open Questions in the final consideration and decision process

- Which are the criteria for a conclusive assessment:
Benefit? Morbidity? Mortality? Prevalence? Costs of treatment? Are alternative therapies available?
Context of treatment (in-patient, out-patient)?
Resources?
- Balance or ratio of these criteria in the final consideration process? Could the final consideration process get standardized?
- How could the transparency and understandability of the final consideration process be improved?

Summary:

- **The G-BA is the main institution authorised by law to issue directives for implementing innovations which are binding on sickness funds, the insured population, panel physicians and hospitals.**
- **The G-BA has different goals in benefit assessment in the areas of in-patient versus out-patient care.**
- **The process of benefit assessment is based on the criteria of evidence-based-medicine.**
- **The G-BA relies on IQWiG recommendations about the benefit assessment.**
- **The Directives can reduce or exclude SHI reimbursement if the assessment does not prove medical necessity and efficiency.**
- **Directives are under the legal supervision of the Ministry of Health.**