



Gemeinsamer  
Bundesausschuss

# The Tasks of the G-BA in pharmaceutical care

Meeting

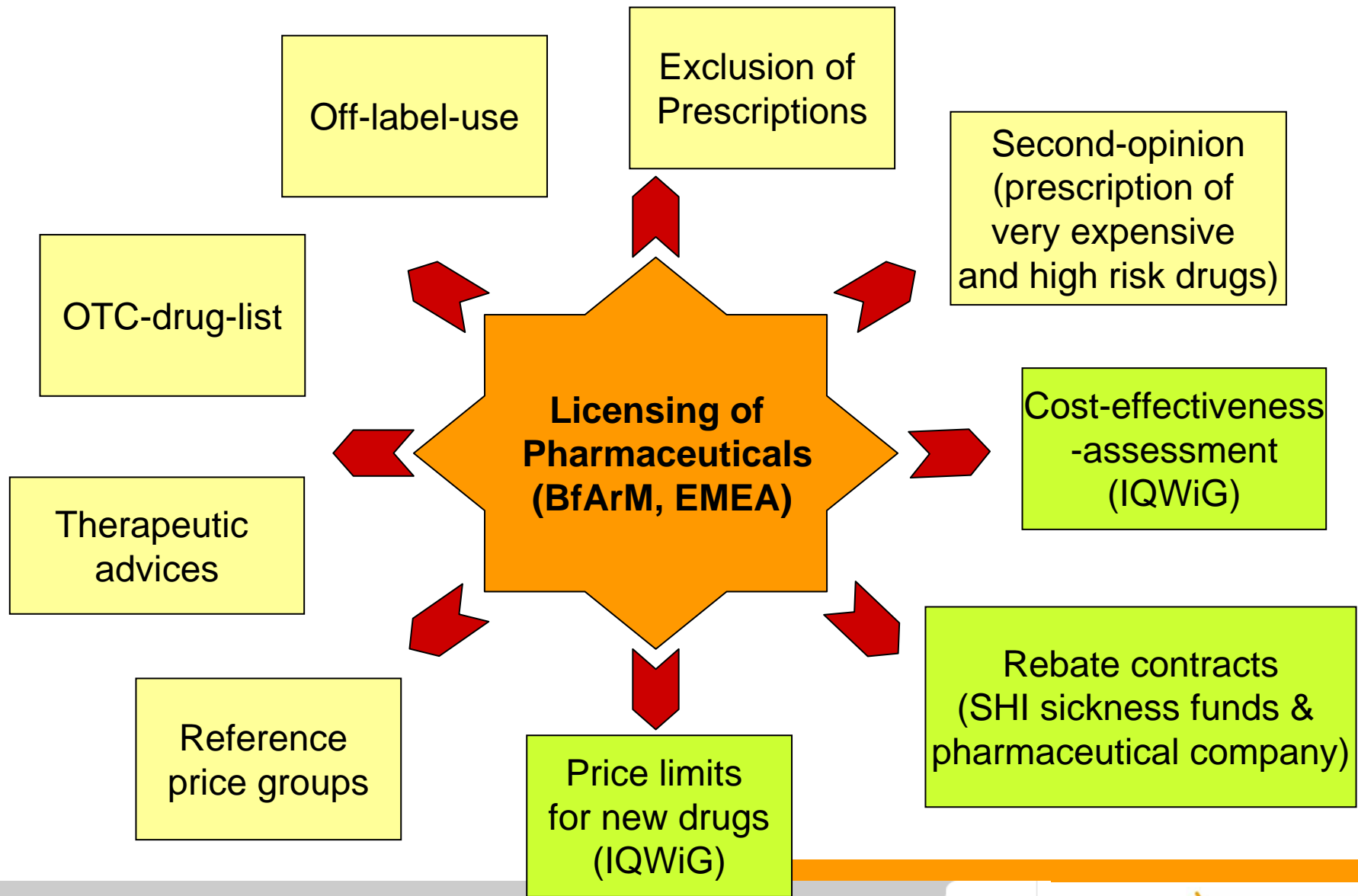
College voor zorgverzekeringen (CVZ) and  
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## Legal Basis of pharmaceutical care:

- 1) Licensed drugs can be prescribed by office-based panel physicians immediately after licensing and must be reimbursed by the SHI sickness funds (with only few exceptions). The price is defined by the pharmaceutical company.
- 2) Restrictions:  
After licensing of new pharmaceuticals in most cases prescription or reimbursement is regulated by directives of G-BA or other legal regulations.

# Pharmaceutical Care



## **Restriction through reference price groups:**

Most licensed drugs with compulsory prescription can be prescribed by office-based panel physicians and get reimbursed by the SHI sickness funds up to the reference price group.

## **Restrictions by G-BA:**

- **Reference price groups** for comparable drugs
- **Limited reimbursement** because of minor or no additional benefit in relation to cheaper drugs.

## Cost benefit assessment by the G-BA:

### Basis of assessment:

Principles of Evidence-based Medicine, in particular Randomized Controlled Trials (RCT's) with patient-relevant endpoints (mortality, morbidity, quality of life)

### Exemption of a drug from a reference price group:

- if it has a **relevant additional benefit** in relation to other in reference price group included drugs,
- if negative **side effects are significantly lower**.

### Possible result:

The sickness funds have to pay the price set by the company; if an additional benefit is proved only for defined indications or patient groups, prescription of this drug outside these indications or patient groups can be limited or excluded.

## Cost/benefit assessment by G-BA:

**Prescription excluded or limited by G-BA directives** under the following conditions:

- **Benefit assessment by the IQWiG**
- **Recommendation of the IQWiG** to the G-BA
- **Final assessment by the G-BA** including economic and care aspects.

### **Possible Result:**

- Therapeutic advice to physicians
- Reference price group with comparable drugs
- Exclusion or indication-related limitation of prescription (exception: single-cases)

## Exclusions of prescriptions:

Licensed drugs available “over the counter” in principle cannot be reimbursed by the social healthcare system (legal restriction by the Social code book V ).

### **Exception:**

- **OTC- drug-list** decided by G-BA including drugs, which are therapeutic standard for the treatment of severe illnesses.

## Off Label Use directives:

Licensed drugs in principle will only be reimbursed for approved indications.

### **Exception:**

- **Off Label Use-directives** by G-BA, allow prescription for non licensed indications under defined conditions and by consent of the producing pharmaceutical companies.

## Pharmaceutical care in hospitals:

In **hospital care** pharmaceutical costs are included in DRGs; price and delivery conditions are negotiated between the companies or wholesalers and the hospital.

- The G-BA has **no legal competence** for regulations.

## Summary of G-BA regulations in pharmaceutical care:

- **OTC – List** with legal exceptions for therapeutic standards.
- **Off-Label-Use Directives** to allow prescription out of licensed indications.
- **Reference price groups** for equal or similar drugs as a basis for reference price settings of sickness funds.
- **Exclusion or limitation of prescription**, if the drug has no or no additional medical benefit in relation to other drugs.
- **Pharmaceutical directives** with therapeutic advice to physicians.