

Appropriate Instruments Providing Pharmaceutical Care

German solutions and problems

Dr. Rainer Hess

Provision of pharmaceutical care must include
price, volume, quality

Germany manages these criteria on five levels

1. free market access under controlled conditions
2. Early benefit assessment of new pharmaceutical agents
3. Negotiation of reimbursement price
4. Compulsory and negotiated discounts
5. Checking physicians' prescriptions and pharmacies' delivery

free market access:

1. National (BfArM) or European (EMA) board
2. Market access combined with restrictions
3. 90% outpatient prescription; 10 % inpatient use only for inpatient care
4. Legal based distribution chain with fixed discounts for Industry (7 %) and fixed marges for wholesalers (3,15 % + 70 Cent and pharmacists (3 % + 8,35€)

early assessment:

1. Consequence of free market access
2. takes place within three months after market access of a new pharmaceutical agent, within an overall procedure lasting one year, during which the sickness funds have to pay the market price
3. guarantees early supply of innovations
4. gives early advices to the prescribing physicians

early assessment of the benefit:

2. Is based on a comparison between the new agent and existing standard therapy in which the company must prove additional benefit by clinical studies to justify a higher price than is paid for the standard therapy
 - 2.1 The price is based on a proved additional benefit and its value
 - 2.2. but in case of withdrawal of the drug from the market, the company “blackmails” patients with the dangers of transferring back to an alternative therapy.

Reimbursement price negotiation:

1. Without proved additional benefit no price negotiation = the price of the existing standard therapy is the upper limit for the new agent;
2. Price negotiations are based on the extend of the value (minor, considerable, substantial);
3. The reimbursement price cannot be introduced before the end of one year;
4. Regulary reviews in special for new agents to treat chronical deseases are necessary.

Rebate and Discount Negotiations:

1. Discounts negotiated with individual sickness funds
2. In the *generic* market competition below legally based reference prices set by the federal sickness fund,
3. Volume-based down-scaling, yearly turnover negotiation with compensation payment for exceeding the turnover, reimbursement depending on measurable medical results (pay for performance)
4. These discount negotiations also are possible and increasing for completely *new agents* replacing the central reimbursement price

Co-payment:

1. The patient has to pay a co-payment in the pharmacy with 10 % of the price but not more than 10 € for a drug;
2. If the co-payment for all prescriptions in a year will succeed more than 2 % of the brutto income of the patient (1 % for certain chronic diseases), he will be deliberated from copayment by his sickness fund.

Economic Check of Drug Prescribing:

1. Sickness funds and panel doctors associations (KV) negotiate at state level an assumed expenditure growth level for the following year and set targets to reach it (share of generics, me-toos, special needs, DDD recommendations, leading agent).
2. As a basis for the check all drugs prescribed are recorded in a computerized system allowing sophisticated comparisons between equal groups of physicians