Stefan Greß

*International experiences striving for sustainability*

*Regulation of drug spending in Germany*

Pharmaceutical Policy Research Collaboration, Toronto, 10 May 2010
## Mixed Set of Policy Instruments

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Price stops and mandatory rebates

- Industry is free to determine prices
- Policy instruments only cover social insurance
- Permanent mandatory rebate for sickness funds
- Price stops and increased mandatory rebates: Blunt instrument to contain costs
  - Negative incentives for innovation
  - List price may increase (external reference prices abroad)
  - Private insurers demand to participate
  - Temporary use
Reference prices

- Introduction of internal reference price system in 1989
- Two-step process
  - Homogenous reference price group (mostly generics – but some patents as well) determined by joint committee of health care providers and sickness funds
  - Reference price determined by peak organization of sickness funds (price in the lower third of the group)
- Reference prices highly effective
  - Industry lowers price to reference price level (and below)
  - Patients extremely reluctant to pay higher prices
  - Lower prices in the reference price part of the market are compensated for in the non-reference price market
Spending caps for physicians

- No strict spending caps – but physicians face the threat of repayment in case of overprescribing
  - If they exceed average prescribing rates by more than 25%
  - Opportunity to justify overspending (e.g. case-mix of patients)
- Highly unpopular with physicians
- Incentives for providing less expensive products
  - Average price for generics is way below reference price
- Incentives for rationing
  - Physicians may avoid overspending by dumping expensive patients or by denying patients expensive medication
User fees

- Ten percent co-payment for prescription drugs
  - Lower limit and upper limit
  - Yearly limits for chronically ill and low-income individuals

- Co-payments do decrease consumption
  - 12 percent of patients refrain from filling a prescription due to co-payments

- Highly effective in conjunction with reference prices
  - Very rarely industry determines prices above the reference price
  - No co-pays for products priced 30 percent below reference price since 2007
  - Huge drop of prices
Negotiated rebates on the sickness fund level 1/2

- Sickness funds may invite tenders for generics
  - High-volume contracts
  - High market share of market leaders (40 percent+)
  - The winner takes it all: fierce price competition for tenders
- Drugs with negotiated rebates …
  - …are exempt from user fees (positive incentive for patients)
  - …are exempt from spending caps (positive incentive for physicians)
  - Pharmacies are required to distribute drugs with negotiated rebates – which may vary between sickness funds
Negotiated rebates on the sickness fund level 2/2

- Competitive advantages for sickness funds
  - Considerable cost savings (not published)
  - Economies of scale
  - Supports market concentration

- Strong pressure for industry
  - Small manufacturer may win or lose large market share by winning or losing only a few contracts
  - Big players may cross-subsidize prizes
  - Supports market concentration
Prices in market segments 2008-2010

Source: GKV-Arzneimittelindex
In a nutshell

• Regulation involves key players – industry, physicians, patients, pharmacies and sickness funds
• Regulation of reference price market is highly effective – strong pressure on prices and choice of product by a mix of instruments
• Regulation of non-reference price market is ineffective
  – Industry is free to determine prices…
  – …which in turn determine prices abroad as well
  – No national formulary
  – Cost-effectiveness of me-too drugs not determined
  – Compensation of losses in the reference price market