Pharmaceutical regulation in Germany: an overview

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Structure

- Decision-making in German health care
- Expenditure for pharmaceuticals
- Market interventions (and their effects)
Statutory health insurance 2000

**Federal Ministry of Health**

**Freedom to choose**

**Federal Assembly (Bundestag)**

**Obligation to secure hospital care**

**Federal Council (Bundesrat)**

**Statutory health insurance 2000**

**Federal Parliament**

**Freedom to choose**

**Obligation to secure hospital care**

**Representation**

**State Ministries responsible for health**

**Legislative frame**

**Supervision**

**Obligation to secure hospital care**

**Obligation to treat**

**Freedom to choose**

**Supervision of regional funds**

**State Ministries responsible for health**

**Obligation to contract**

**Financial negotiation**

**Physician**

- 23 (Regional) Physicians' Associations
- Federal Association of SHI Physicians

**Hospital**

- 16 Regional Hospital Organizations
- Federal Hospital Organization

**Sickness fund**

- Sickness funds in one region

**Federal associations of sickness funds**

**Coordinating Committee**

**Fed. Com. of Physicians and Sickness Funds: Decisions on ambulatory benefits**

**Valuation Committee: Setting of relative point values**

**Fed. Com. for Hospital Care: Decisions on in-patient benefits**

**DRGs: Decision about types and valuation**
Figure 1: Number of prescriptions per insurant and year

Source: VFA, Statistics 2002, 2002 (package size has not changed significantly over the years)

Figure 2: Growth of the total pharmaceutical market in Germany (in billion €)


The German pharmaceutical market is big – and growing!
... faster than overall health expenditure
(which in turn is growing faster than the economy as a whole)

Figure 3: Pharmaceutical expenditure as % of health expenditure
It’s not the prices per se!
Figure 6: Production, distribution and funding of pharmaceuticals in Germany in 2001

Figure 7: Composition of retail prices

Source: VFA 2002.
Market interventions

Figure 8: Types of market interventions in the German pharmaceutical market

- price reductions
- reference pricing
- co-payments
- “aut-idem”
- parallel imports
- negative list
- positive list
- guidelines
- spending caps (for physicians/physicians’ associations)
- pharmacy rebate for SHI

SPENDING CONTROLS

PRICE CONTROLS x VOLUME CONTROLS = SPENDING CONTROLS
Supply-side

- Price reductions (various times; usually for non reference-priced drugs)
- Reference-pricing
- Pharmacy rebate for SHI
Figure 10: Reduced expenditures for sickness funds due to reference pricing

Source: BKK for various years; VFA 2002.
Somewhat contradictory ...

Figure 11: Market share of reference-priced drugs as percentage of the total pharmaceutical expenditure

Source: BKK for various years, Boehringer Ingelheim 2002.

These data seem strange as patented drugs only account for around 20% of total pharmaceutical expenditure.
Lies, IMS, and the pharmaceutical industry?
Demand-side

• Co-payments
• Negative list (since 1983)
• Positive list (1st attempt failed 1995; 2nd currently about to fail)
• Spending caps (since 1993; until 2001)
• „Aut-idem“ substitution
• Parallel imports
• Guidelines
Co-payments: up and down (in EUR per pack)

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# Budgets and spending caps since 1989

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<th>Ambulatory care</th>
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<td>target budgets at hospital level</td>
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<td>practices</td>
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**Failed attempt to introduce global budget**
<table>
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<th>Action</th>
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<tr>
<td>Act to Newly Regulate Choice of Sickness Fund</td>
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<td>Act to Introduce the Residency Principle for Physicians’ and Dentists’ Reimbursement</td>
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<td>Act to Reform the SHI Risk Adjustment Mechanism</td>
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<td>Act to Adjust Reference Price-Setting Regulations</td>
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<td>Act to Limit SHI Pharmaceutical Spending</td>
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<td>Act to Introduce a Case Fees-System in Hospitals</td>
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Measures 2002

- Guidelines & voluntary limitations
- Increased pharmacy rebate
- „Aut-idem“ substitution
- Parallel import requirements tightened
Figure 9: Random test on substituted prescriptions in southern Germany

5611 prescriptions of products with an existing substitution line

1324 prescriptions above substitution line
= 23.6%

4287 prescriptions below substitution line
= 76.4%

250 substitution excluded
= 18.9%

1074 substitution approved
= 81.1%

585 substitution excluded
= 13.5%

3702 substitution approved
= 86.5%

Market share parallel imports (compared to legal minimum)

% am GKV-Arzneimittelmarkt

Quelle: IMS

Pflichtquote gem. Vertrag zwischen DAV und GKV
Currently proposed in Health Care Modernisation Act

• „German Centre for Quality in Medicine“ charged with fourth hurdle
• Immediate reference-price if no added benefit
• Higher co-payments, lowered for patients in disease management programmes etc.
• OTC no longer prescribable (except children and certain indications)
Preisentwicklung von erstatteten Arzneimitteln rezeptpflichtig versus nicht rezeptpflichtig

Preisindex (Jan. 2001 = 100)