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Peer Review: Cost containment in the pharmaceutical sector

**Rebate negotiations on
pharmaceutical prices between
statutory health insurances and
pharmaceutical producers
- Experiences from Germany -**

Berlin, 30 June 2008

Two days conference on behalf of the
European Commission DG Employment, Social Affairs and
Equal Opportunities



Rebate negotiations on pharmaceutical prices

Overview

- Legal Regulation in Germany
- Handling of Rebates
- Rebates and the regulatory system
- Contracts on Rebates
- Experiences in Germany
- What's next
- Recommendations



Legal Regulation in Germany (1)

- One RX Package has the same price in every pharmacy
- Pharmaceutical Companies have to sell an RX-Package at the same Ex-Factory Price
- Fixed Margins for
 - ◆ Wholesalers (4 % on average)
 - ◆ and Pharmacies (3 % plus 8,10 Euro per package)

§ 78 Abs. 3 Arzneimittelgesetz



Legal Regulation in Germany (2)

- Pharmaceutical Companies may pay rebates only to
 - ◆ health insurances (public or private)
 - ◆ state agencies covering health care (army, civil service)

§ 78 Abs. 3 Arzneimittelgesetz

- Pharmaceutical Companies may contract with public Health Insurances
 - ◆ Rebates on RX-Packages
 - ◆ Budgets for overall sales
 - ◆ any other agreements for Rebates

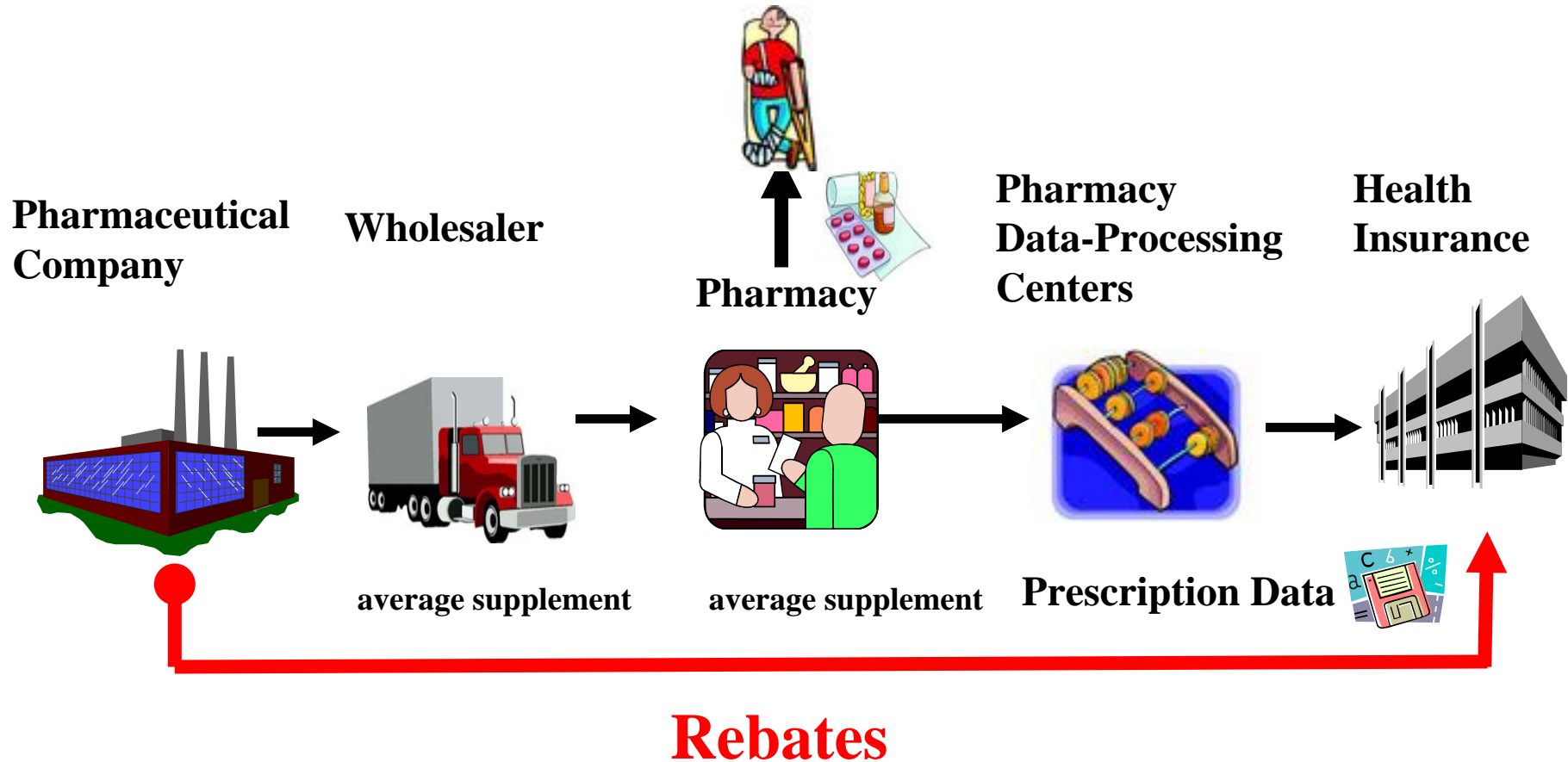
§ 130a Abs. 8 Fünftes Buch Sozialgesetzbuch

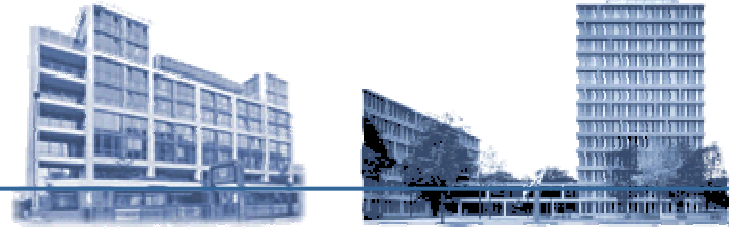


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Handling of Rebates

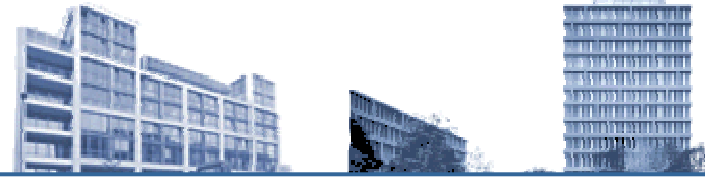




Rebates and the regulatory system

Rebates are integrated in

- Germany's Health Care System
- Germany's Regulation for Pricing and Reimbursement



Germany's Health Care System

- Health care is **insurance based**
- **Every Resident** has to take insurance
- Non-profit funds ["Krankenkassen"] cover 90 % of the population
- **Free choice** of health insurance funds, of private doctors, hospitals, pharmacies, other services
- **One, standard list of medical benefits**
- **Corporate contracting** with associations of providers
- **NEW**: single contracting with physicians, hospitals etc: HMOs / PPOs tariff



Germany's Regulation for Pricing and Reimbursement

Drug Coverage by Health Insurance Funds

- Price-Limits for Reimbursement
- Fixed Reimbursement Amounts
 - Maximum Reimbursement Price
 - **Rebates**

- Prescription - Limits
- Drugs excluded by Law
 - Guidelines and Directives
 - Prescription volume targets

Benefit/ Cost-Benefit - Analysis



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**Generic
substitution**
„aut-idem“
§ 129 SGB V

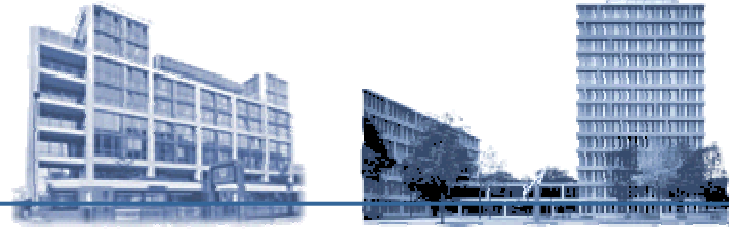


Office based Physicians



Patients
Co-Payments

- **Contracts on Prescription-Lists (§ 84 Abs. 1 SGB V):**
- **Release from Prescription Limitations (§§ 84, 106 SGB V)**
- **Bonus (§ 84 SGB V)**
- **Participation in Rebate Contracts (§ 130a SGB V)**



Experiences in Germany (1)

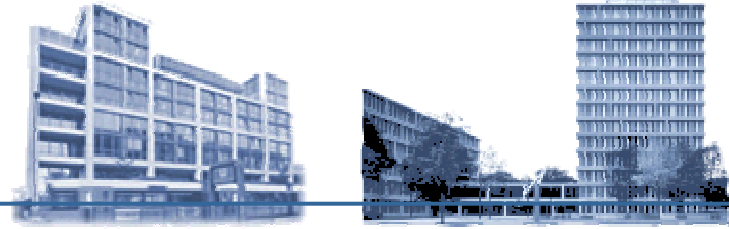
- 390.000 contracted Rebates
 - ◆ Generics: 97,6%
 - ◆ Off-Patent Originals: 0,4%
 - ◆ Patent protected: 2%
- Rebate-Drugs Share of Total Sales (Packages)
 - ◆ Generics : 30 %
 - ◆ Patent Protected: less than 1 %
- Savings: 100 mln € / 6 months = 1 % of expenditure

Experiences in Germany (2)

- Germany's Public Procurement Chambers fully apply the Directive 2004/18/EC on public contracts – but this is contradicted in national court trials
- If a complaint is raised, the Chambers have stopped every single contract
- Huge controversies:
 - ◆ Are rebate-agreements public contracts?
 - ◆ Can Health insurers join a buying syndicate?
 - ◆ Do contracts have to be limited to the supply of smaller regions ?
 - ◆ Can Health insurers contract on bundles/ groups of pharmaceuticals?
 - ◆ Can Patent protected Drugs be included ?



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Rebates: What's next ? (1)

Can a Contract-System replace the corporate
Regulations on Prices + Prescription ?



Rebates: What's next ? (2)

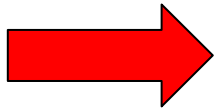
- Can Contracts cover all drugs subject to fixed reimbursement amounts ?
 - ◆ less than 100 % of Generics covered
 - ◆ Most of Me-too Drugs are not covered
- Can Patent protected Specialties be covered ?
 - ◆ Contracts on Managed Care required
 - ◆ Physicians have to cooperate
- Can medical benefits for innovative drugs be subject to the decision of single health insurers ?
- Do the contract-regulations insure the purchase of all required medicines on time and at affordable prices?



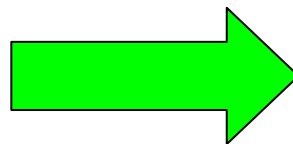
Rebates: What's next ? (3)



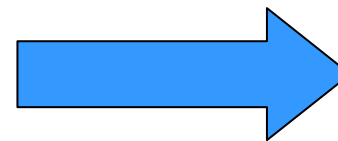
Rebates on Generics



Rebates for Me-Too s



+ Cost / Risk Sharing
/ Budgets



+ Prescription
Guidelines



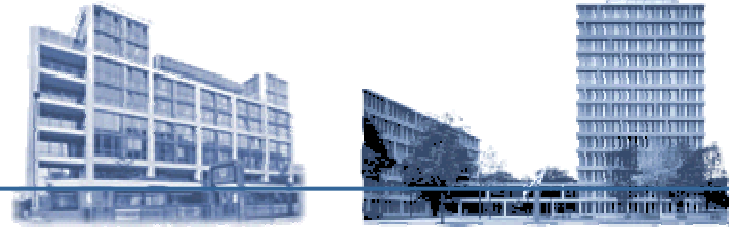
Cost
Reduction



Cost
Effectiveness



Managed Care



Conclusions + Recommendations

- The Contract System for Pharmaceuticals is still experimental
- Supply of Pharmaceuticals up to now can not be covered by Contracts
- New Managed-Care Concepts for the supply of innovative Drugs have to be developed
- The Contract System requires Regulations to ensure Equal Access of Patients to Innovations
- It is uncertain, if the legal Framework will allow cost-saving contracts on time



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Any questions ?

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