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Reference Price System in Germany

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Federal Ministry of Health

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Pricing and Reimbursement

- Free pricing for ex-factory Prices
- Reimbursement limited by reference-prices
- Rebates for products free from reference-prices: 6 %
- Generic-Drug-Rule for Low-Price-Products: health insurance can decide on supplier by contract (aut idem)
- Co-payment 10 %, min. 5 Euro; max. 10

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Reference Pricing in Germany

- Two-step-process
  - Grouping of pharmaceutical substances - Federal Committee (Sickness Funds & Physicians)
  - Establishing Reference prices - Sickness funds (Federal Association)

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Grouping of pharmaceuticals

- Type 1
  - Same pharmaceutical substances
- Type 2
  - Similar pharmaceutical substance und medical effects
- Type 3
  - Similar medical effects
- **Priority for Grouping in Type 2**

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Grouping in „Chemical Families”

- Starting with ATC-Classification on level 4
  - 1: C CARDIOVASCULAR SYSTEM
  - 2: C10 SERUM LIPID REDUCING AGENT
  - 3: C10A CHOLESTEROL AND TRIGLYCERIDE RED.
  - 4: C10AA HMG CoA reductase inhibitors
    - C10AA01Simvastatin
    - C10AA02Lovastatin
    - C10AA03Pravastatin
    - C10AA04Fluvastatin
    - C10AA05Atorvastatin etc.

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Grouping of pharmaceuticals

- Considering Patent-status
- Considering therapeutic innovations
- Calculating equivalence factors

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Considering Patent-status

- New substance/ Soloist = no grouping
- Patent-only-group: minimum three products
- First product out of patent: Generics may be grouped with drugs still under patent ("Jumbo-Groups")

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Regarding therapeutic innovations

- Therapeutic innovation= substance with added medical benefit than other substances in the same class:
- Reduction of side-effects is also respected
- Therapeutic innovations must not be grouped

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Therapeutic Innovation

- All grouping is based on clinical evidence
- Reports have to be published
- Pharmaceutical companies have to be asked to give their comment on all propositions for grouping
- Grouping is supervised by the Ministry of Health
- All groups may be revised by court

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Calculating Equivalence-Factors

- Grouping covers more than one chemical substance
- Equivalence factor compares doses of substances
- Calculation from actual sales data: average dose per unit and package
- adjustments according to frequency and terms of use
- factor is strictly calculated, no manual adjustment

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Establishing Reference Prices

- One price for „reference package“
- All package sizes and doses per unit are covered by regression analysis formula
- Price-Level:
  - patent- only- groups: maximum price of lower 50 % of price range
  - All other groups: maximum price at lower 30 % of price range
  - Strictly calculated, no manual adjustment
- Reference prices are adjusted once a year

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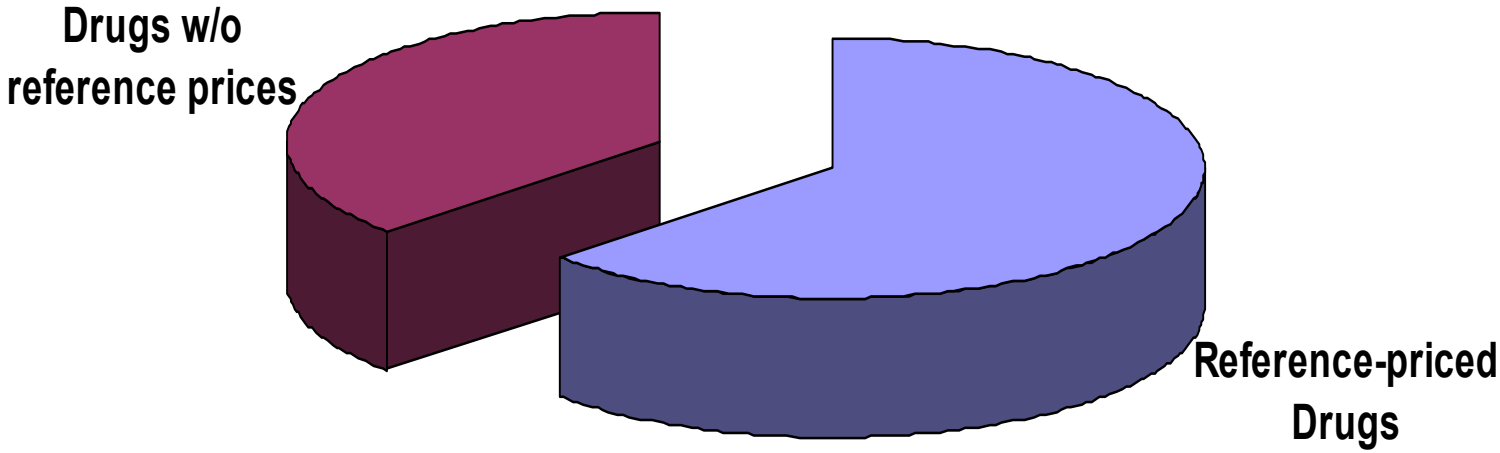
Prescription of reference-priced drugs as % of total (2007, Jan-March)

source: GAmSI



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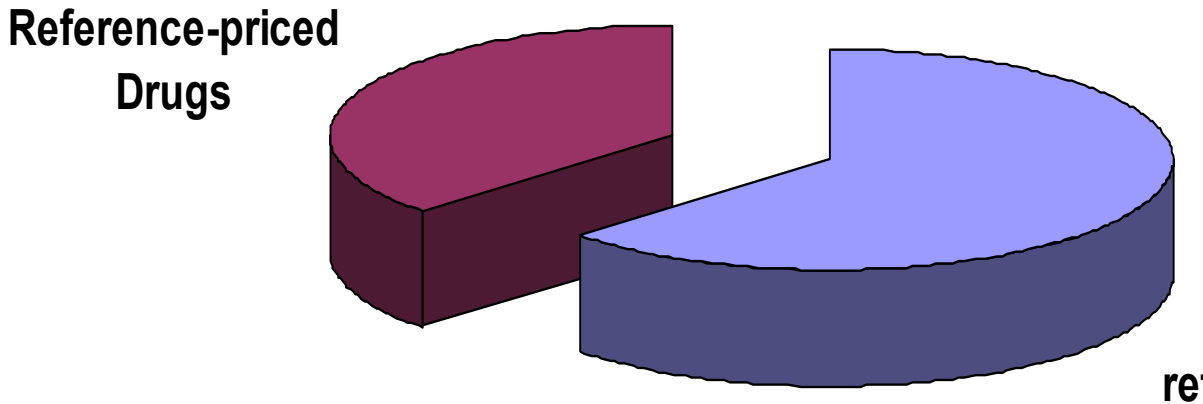
Sales of reference priced drugs
as % of total
2007, Jan-March

Source: GAmSI



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Thank you for you for your attention !

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