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***International experiences striving for sustainability
Regulation of drug spending in Germany***

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Mixed Set of Policy Instruments

	Direct	Indirect
Centralized on a national level	<ul style="list-style-type: none"> • price stops • mandatory rebates 	<ul style="list-style-type: none"> • reference prices • spending caps for physicians • user fees
Decentralized on the sickness fund level	<ul style="list-style-type: none"> • negotiated rebates 	<ul style="list-style-type: none"> • user fees • exemptions from spending caps



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

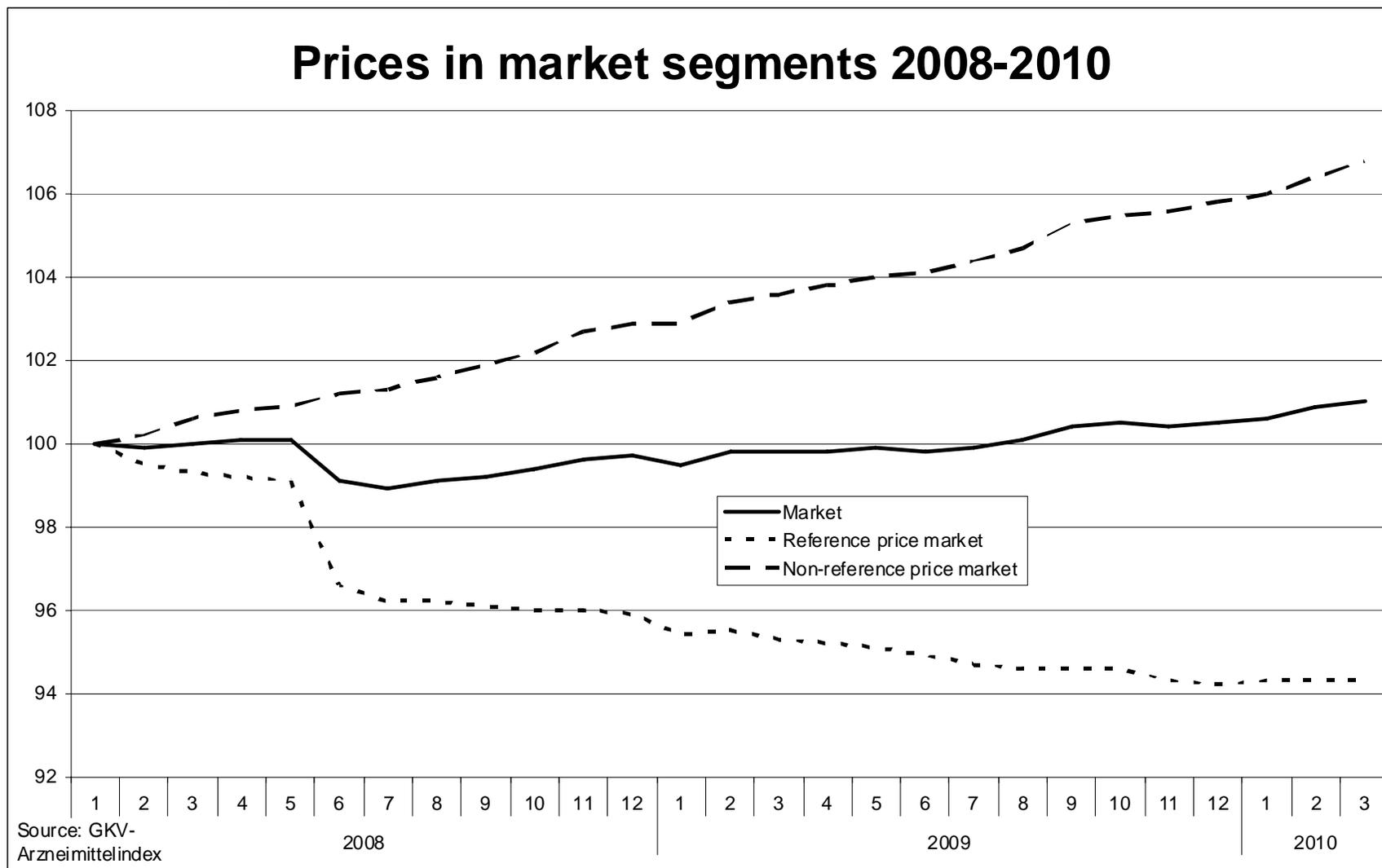


Negotiated rebates on the sickness fund level 2/2

- 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

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Regulation of drug spending in Germany



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