

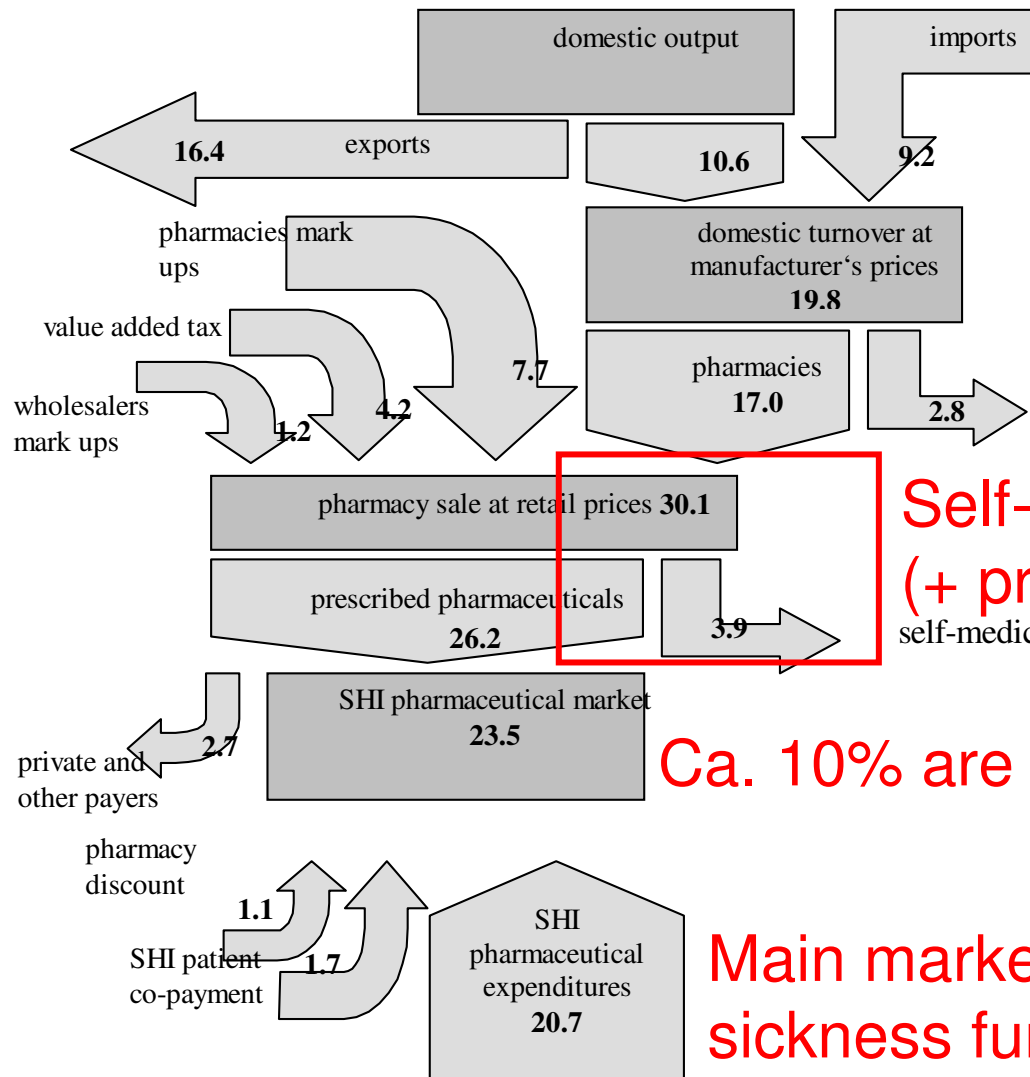
Pharmaceutical regulation in Germany: an update

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Production, distribution and funding of pharmaceuticals in Germany in 2001



Large industry (115,000 employees), largest drug exporter, big export surplus

Self-medication (OTC) = 13% (+ prescribed „OTC“ 10%)
self-medication

Ca. 10% are privately insured

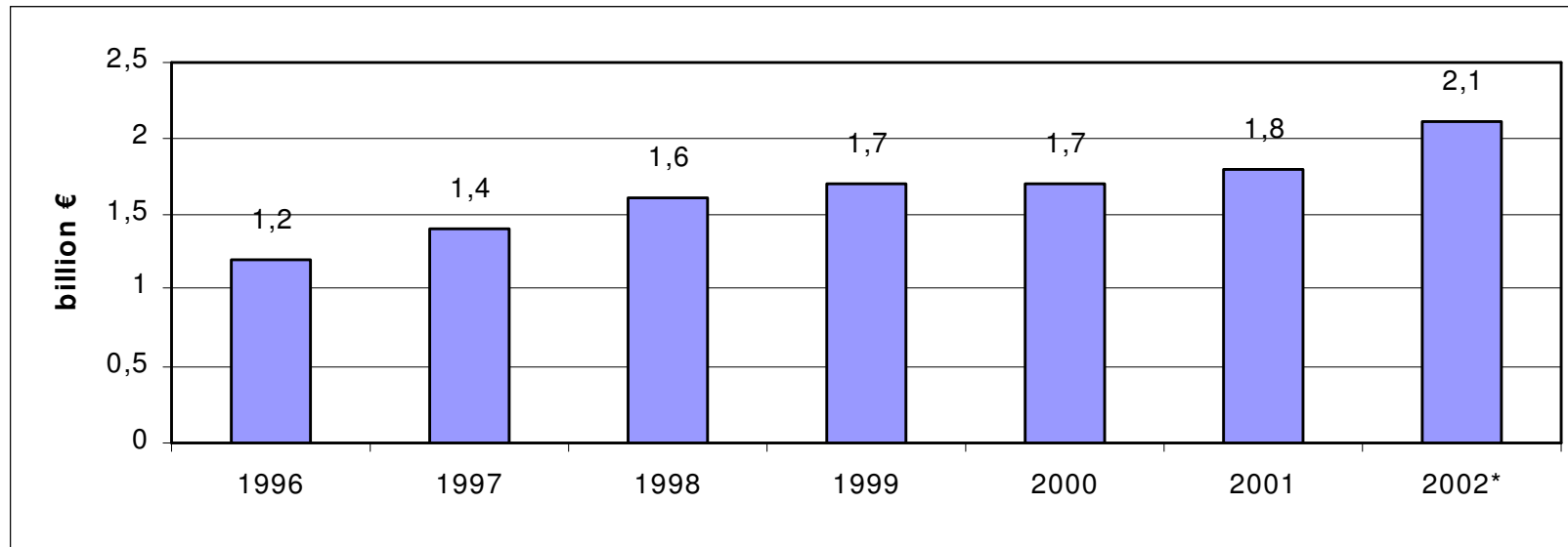
Main market are drugs covered by SHI sickness funds (which get 6% discount); copayments of EUR 4-5 cover 8%

Measures to control costs 1

- Co-payments (old instrument, many ups and downs)
- Negative list (since 1983)
- Prescription guidelines by Federal Committee of Physicians and Sickness Funds
- Reference-pricing (since 1989)
- Price reductions (various times; usually for non reference-priced drugs)

Patented drugs excluded since 1996!

Reduced expenditures for sickness funds due to reference pricing



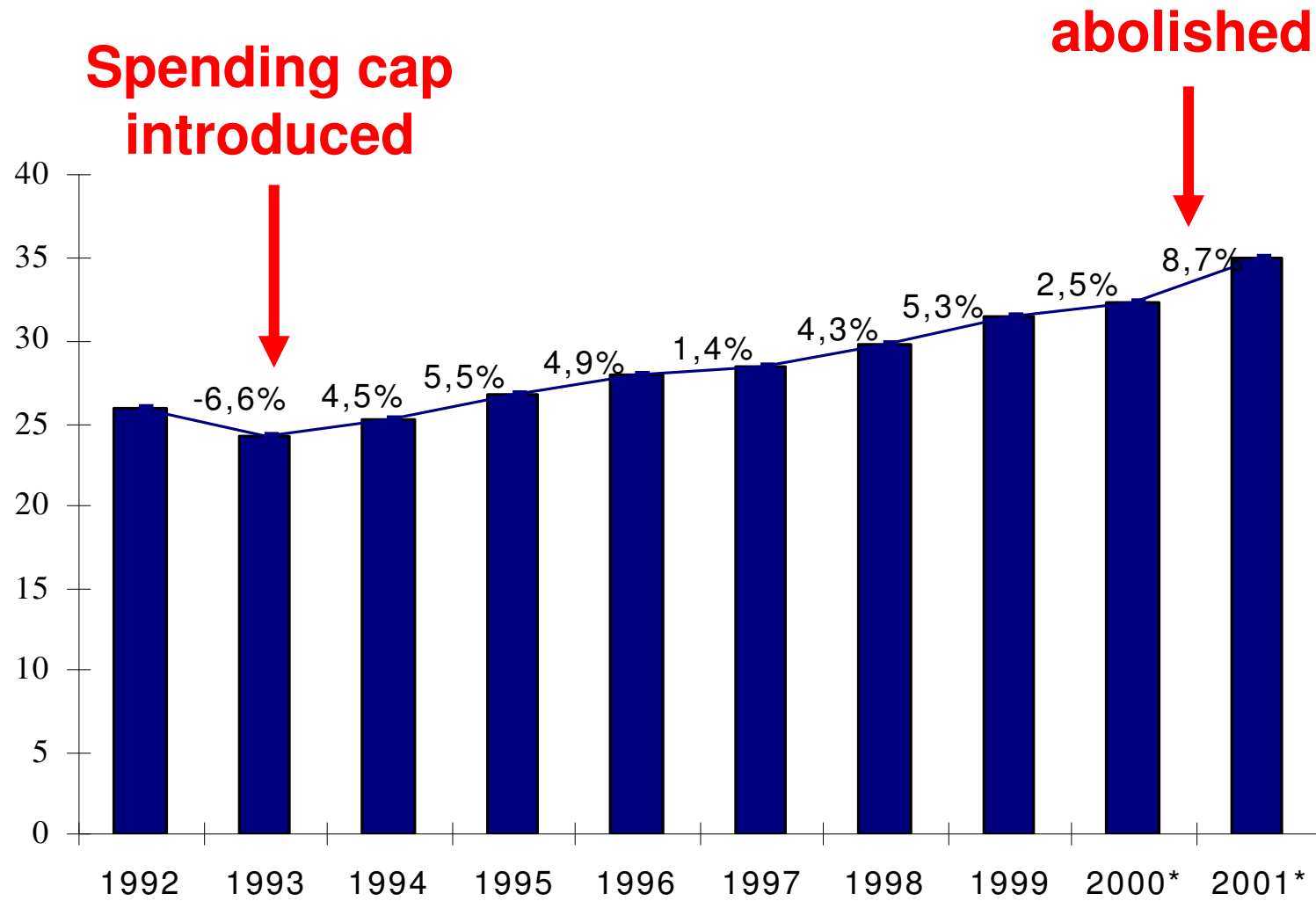
Source: BKK for various years; VFA 2002.

= ca. 9% of SHI
pharmaceutical
expenditure

Measures to control costs 2

- Parallel imports
- Positive list (1st attempt failed 1995; 2nd version currently in Parliament)
- Parallel imports
- Pharmacy rebate for SHI (was 5%, now 6-10%)
- Spending cap for prescribed drugs (with claw-back threat for industry & physicians in 1993; later physicians only)

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



Source: VFA, Statistics, 2002.

Measures 2002

- Planned price reduction was prevented by industry for a price of EUR 200 million
- Guidelines & voluntary limitations
- Increased pharmacy rebate
- Parallel import requirements tightened
- „Aut-idem“ substitution: pharmacist is required to substitute for cheaper product if *physician has not rules out substitution* and if *prescribed drug is above threshold*

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)