



AMNOG Chances and risks

The new drug reimbursement law in Germany

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German drug market

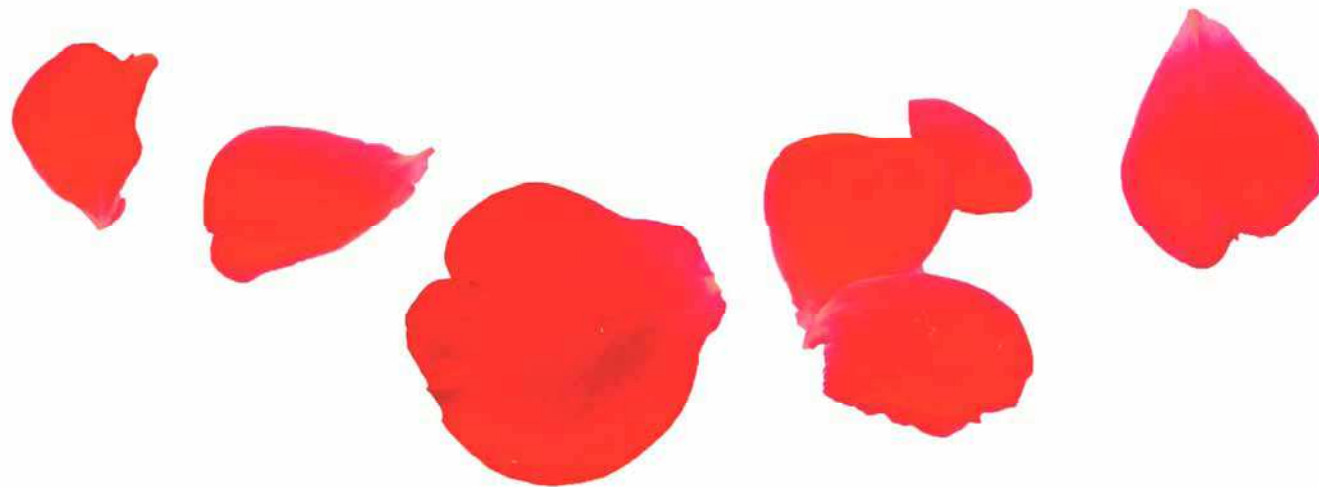
Before 2011: Anything goes

- Public health insurance paid for all Rx drugs
- Manufacturer free to set price
- Price caps (Festbeträge) only with delay and for a limited number of drugs
- Rare exclusions (lifestyle drugs, negative benefit/cost assessment)
- Steep rise in cost of patented drugs
1993 = 11% 2010 = 48%



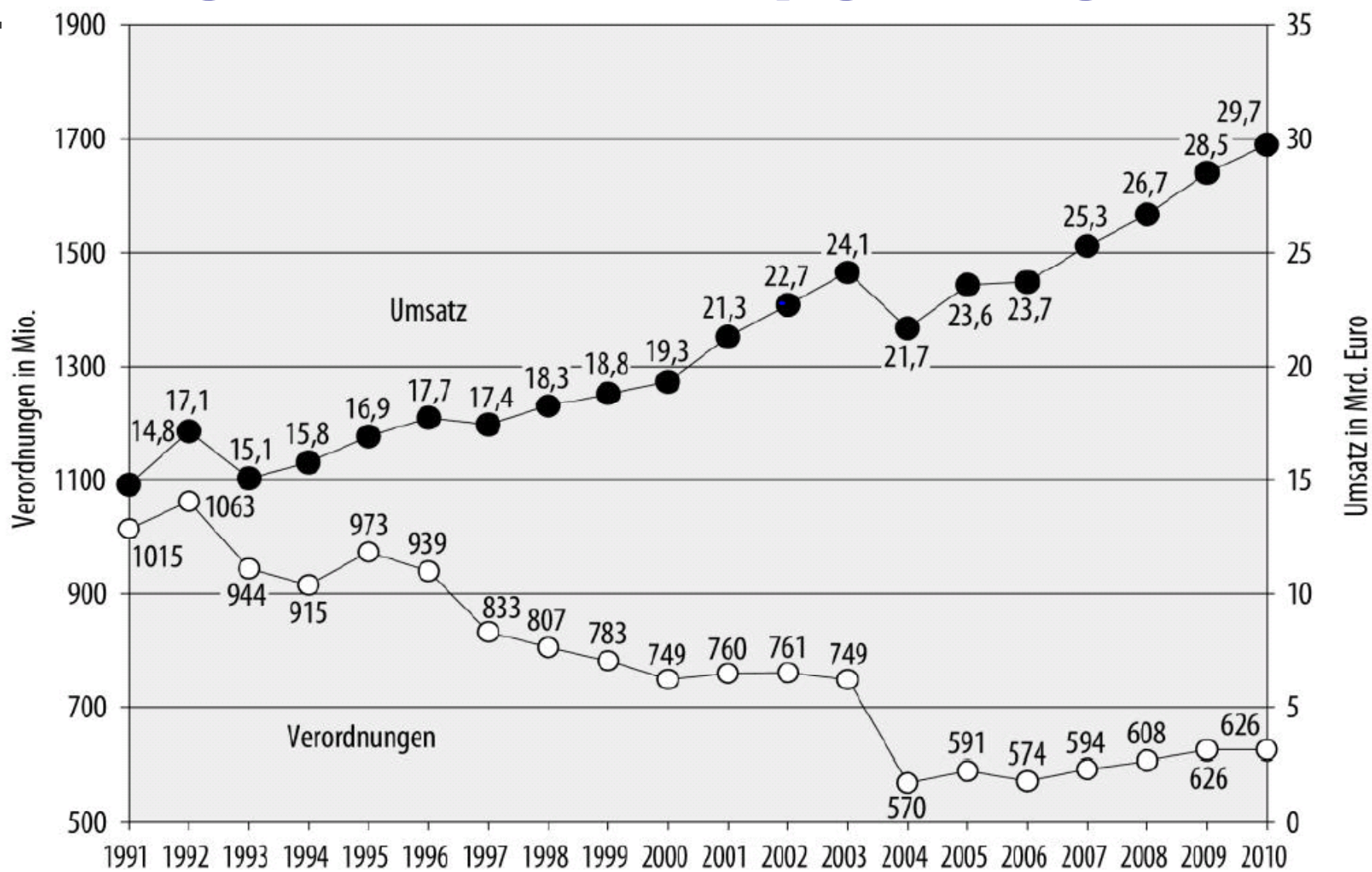
Not so rosy

- Rosiglitazone for diabetes
- More cardiovascular events
- Excluded from reimbursement June 2010
- Banned 1 Nov 2010





Germany: Drug costs constantly growing



Tough discussions

- More money for drugs than for doctors
- Germany drug price reference for ~ 60 countries
- Copy and paste by health ministry



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Benefit – harm ratio counts

- Obligatory early benefit assessment for all new drugs
- Price is regulated after one year
 - ***Additional therapeutic value***
 - > Bargaining between health insurance and manufacturer
 - ***No better***
 - > Same price (cap) as competitor
 - ***Worse***
 - see above

* Arzneimittelmarktneuordnungsgesetz

G-BA Federal Joint Committee

- Public health insurers (Krankenkassen)
- Doctors and hospitals in public system
- Patient representatives (no voting rights)
- Assessments prepared by IQWiG (German NICE)



Limitations:

- Manufacturers still get one year free ride
- EU Orphan drugs are excluded (turnover less than € 50 million/year)
- Early advice (abuse for bargaining)



Difficult to exclude drugs

- Difficult to proof that purple elephants do not exist





Effects so far

- Procedure operational
Law was voted Nov 2010
- Pivastatin
Manufacturer: No better
- Novartis took aliskiren/amlodipin off the market
- Linagliptin
Not marketed at all



Key questions

- Which comparators?
- Who decides about standards of evidence?
- Access to all study data?
- Publishing of study results in the assessment (required by law)?

Separate issue:

- Obligation to publish all trials 6 month after market approval watered down?