AMNOG Chances and risks

The new drug reimbursement law in Germany

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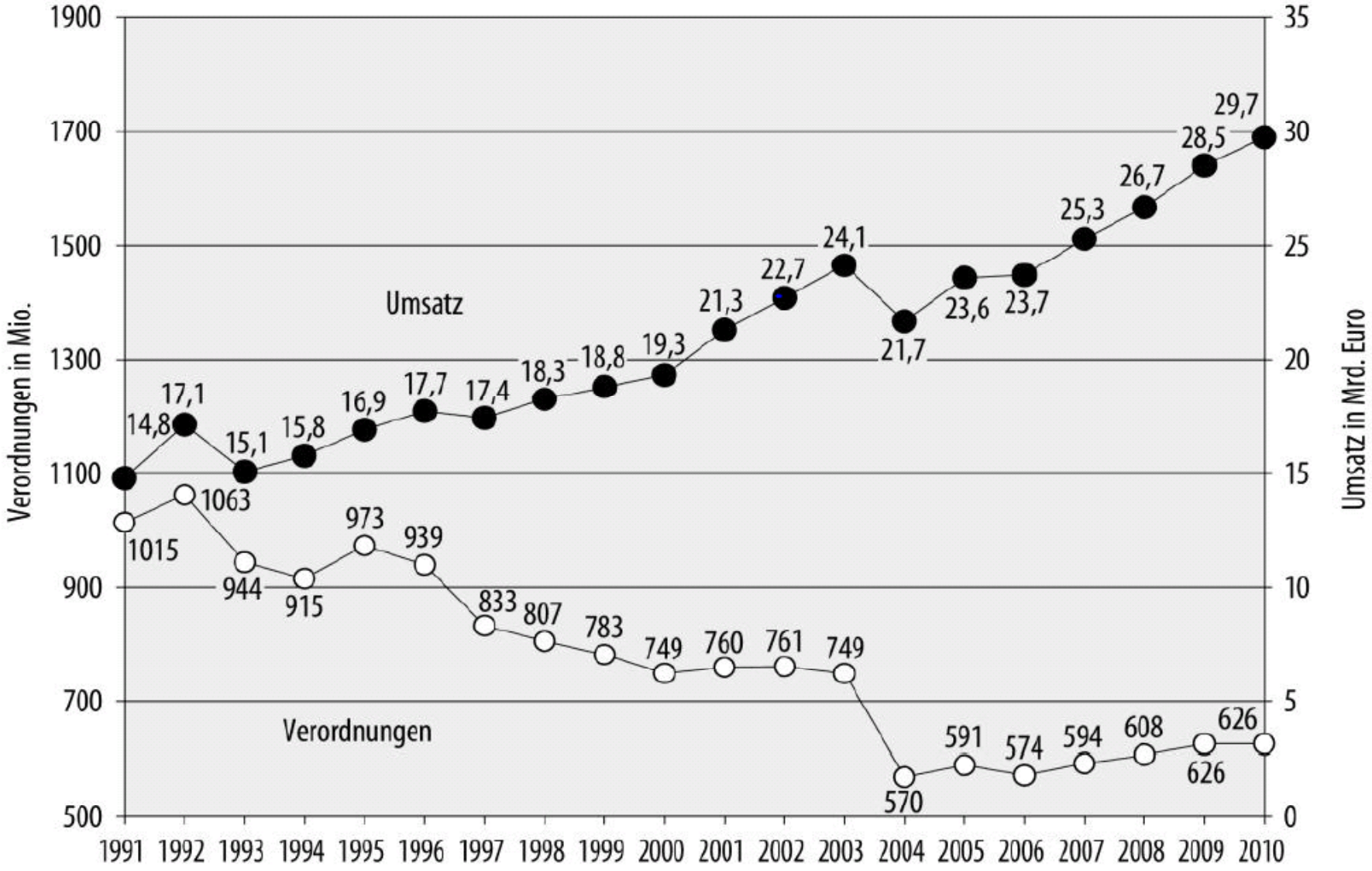
German drug market
Before 2011: Anything goes

- 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

Justin © M

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?