The German health system – status, challenges and reforms

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How we look at health systems

Collector of resources  Third-party payers

Regulator

Population  Providers
The German system at a glance

**Collector of resources**
Health fund

- Uniform (set by law) + additional (set by sickness fund) wage-related contribution rate
- Risk-related premium

**Choice of fund/insurer**

**Strong delegation**
(Federal Joint Committee) & limited governmental control

**Third-party payers**
Ca. 120 sickness funds
Ca. 45 private insurers

- Contracts, mostly collective
- No contracts

**Population**
Universal coverage:
Statutory Health Insurance 86%
Private HI 11%

**Providers**
Public-private mix, organised in associations
ambulatory care/ hospitals

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| London, January 25, 2017 |
Key characteristics (I):

a) Sharing of decision-making powers between the sixteen Länder (states), the federal government and statutory civil society organizations
   i.e. important competencies are legally delegated to membership-based, self-regulated organisations of payers and providers

b) German health care [almost] = Statutory health insurance (SHI)
   SHI Cornerstone of health service provision is the Fifth Book of the German Social Law (SGB V)
   i.e. it organizes and defines the self-regulated “corporatist” structures and give them the duty and power to develop benefits, prices and standards

c) Existence of substitutive private health insurance alongside SHI
Key characteristics (II):

d) Sectoral borders

Provision of ambulatory and inpatient services.
Planning, resource allocation, provision and financing are separate for ambulatory (office-based physicians) and inpatient (hospitals) sector.

→ Complicates the provision of health care delivery
   (problematic especially for chronically ill → answers: Disease Management Programmes and selective “integrated care” contracts)

→ Increases the amount of specialists

→ Increases the health care expenditure

→ Various reforms have tried to lessen sectoral borders (last in 2012 by creating a new in-between sector for highly specialized ambulatory care)
Decision-making in German SHI

Parliament

Federal Ministry of Health

Legislation

Supervision

Patient

150,000 ambulatory care physicians and psychotherapists

Federal Association of SHI Physicians (KBV)

German Hospital Federation (DKG)

120 sickness funds

Federal Association of Sickness Funds

Federal Joint Committee (G-BA)

Members: 13 voting – 3 neutral + 5 sickness funds + 5 providers (+ up to 5 patient representatives)

Statutory Health Insurance
Objectives of Federal Joint Committee

- Main functions: to regulate SHI-wide issues of access, benefits and quality (and not primarily of costs or expenditure)
- **Normative function of the G-BA by legally binding directives (“sub-law“) to guarantee equal excess to necessary and appropriate services for all SHI insured**
- Benefit package decisions must be justified by an evidence-based process to determine whether services, pharmaceuticals or technologies are medically effective in terms of morbidity, mortality and quality of life
- By law, evidence based assessments can only be used to select the most appropriate (efficient) service etc. from others – not to prioritize among service areas: if a costly innovation has a significant additional benefit, the sickness funds must pay for it
Decisions are prepared by 9 sub-committees:

- Pharmaceuticals
- Quality Assurance
- Disease management programs
- Methodological Evaluation (inclusion of new ambulatory care services in benefit basket; NB: in hospitals, services can only be excluded)
- Highly specialized ambulatory care (by office-based physicians and hospitals; new sector since 2012)
- Referred Services (rehabilitation, care provided by non-physicians, ambulance transportation etc.)
- Needs-based Planning (ambulatory care; NB: hospital capacities are planned by state governments)
- Psychotherapy
- Dental Services
G-BA: support through institutes

Parliament

Legislation

Federal Ministry of Health

Supervision

Patient

150,000 ambulatory care physicians and psychotherapists

Federal Association of SHI Physicians (KBV)

German Hospital Federation (DKG)

2,000 hospitals

120 sickness funds

Federal Association of Sickness Funds

Federal Joint Committee (G-BA)

Institute for Quality and Efficiency in Healthcare (IQWiG) – technologies

Institute for Quality Assurance and Transparency in Healthcare (IQTiG) – focused on providers

Statutory Health Insurance

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- Probably the last big change worth mentioning: the AMNOG on drug prices (from 2011)
- Since then, an abundance of reforms, but no big one ...
## Pharmaceutical policies: evaluation and reimbursement

### Important policies regarding patented drugs in Germany since 1996.

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<tr>
<td><strong>Evaluation of additional/comparative benefit</strong></td>
<td>No</td>
<td>Upon application of Ministry of Health or parties in G-BA</td>
<td></td>
<td>Mandatory for all new drugs/indications except orphan drugs (^a) (^b)</td>
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<td><strong>Price-setting</strong></td>
<td>Free by manufacturer</td>
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<td>Officially free by manufacturer, but de facto only for 12 months after launch</td>
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<td><strong>Reimbursability (benefit basket)</strong></td>
<td>All patented drugs included in benefit basket</td>
<td>Drugs without proof of effectiveness or with proven inferior effectiveness or with more efficient alternatives may be restricted or excluded (such as insulin analogues) (^1) (^1)</td>
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<td>Only drugs with proven inferior effectiveness or with more efficient alternatives may be restricted or excluded</td>
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<td><strong>Reimbursement price in case of no additional benefit</strong></td>
<td>Reimbursement = price (possibly temporarily lowered by a certain %)</td>
<td>Drugs are grouped and a reference price is determined per group; patient pays difference between price and reference price (example: atorvastatin [Sortie])</td>
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<td>New drugs are grouped as well and are liable to reference price; if grouping is impossible, price may not exceed that of existing alternative</td>
</tr>
<tr>
<td><strong>Reimbursement in case of additional benefit</strong></td>
<td>Reimbursement = price (possibly temporarily lowered by a certain %)</td>
<td>Maximum reimbursement ceiling may be set following cost-effectiveness analysis (not done in a single case); in other cases reimbursement = price</td>
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<td>Country-wide rebate on manufacturer price is negotiated between Federal Association of Statutory Health Insurance Funds and manufacturer (→ fixed reimbursement price from month 13 after launch)</td>
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<td><strong>Unevaluated drugs</strong></td>
<td></td>
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<td>Reimbursement = price (possibly temporarily lowered by a certain %)</td>
<td>As before (concerns only patented drugs with market launch before 2011 and orphan drugs)</td>
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<td><strong>Cost-effectiveness analysis</strong></td>
<td>No</td>
<td>No</td>
<td>May be commissioned by G-BA for drugs with additional benefit (two analyses commissioned)</td>
<td>If negotiations fail and if one side challenges the result of the arbitration, a cost-effectiveness analysis is commissioned by the G-BA</td>
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\(^a\) Although the additional benefit is deemed to be proven for orphan drugs, a dossier has to be submitted, and price negotiations will follow. The dossier does not have to present proof of the medical benefit and additional benefit. However, the dossier must include information on the groups of patients for whom there is significant medical additional benefit and on the extent of this additional benefit \(^1\) \(^1\). If the business volume of an orphan drug reached the amount of 50 million EUR during the last 12 months, a second (and full) dossier demonstrating additional benefits will have to be submitted within 3 months of its request by the G-BA.

\(^b\) Patented pharmaceuticals that were approved before 2011 are also assessed in the AMNOG process, if it is initiated by the G-BA.
Pharmaceutical policies: evaluation and reimbursement

Fig. 1. Procedure for reimbursement of patented pharmaceuticals source: based on IQWiG [14].
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<tr>
<th>Gesetzesname</th>
<th>Organisati on &amp; Steuerung</th>
<th>Finanzierun g &amp; Vergütung</th>
<th>Ressource n</th>
<th>Leistungs- erbringun g</th>
<th>Arzneimittel / Medizin- produkte</th>
<th>Pflege</th>
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<td>Gesetz zur Verbesserung der Versorgungsstrukturen in der GKV*</td>
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Deaths per 100,000 population*

* Countries’ age-standardized death rates before age 75. List of amenable causes: Nolte & McKee 2004

Source: WHO Mortality Files (number of deaths by age group) and populations (except Human Mortality Database for Canada, UK and the USA). European Standard Population 2013.
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