Hamburg, 2019

Reimbursement of Innovative Pharmaceuticals and Medical Devices in Germany
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Agenda

The German pharmaceutical market

Basic information on German health care system

Reimbursement of innovative drugs

Reimbursement of innovative medical devices

How to find the best reimbursement strategy ?!
The German pharmaceutical market is the 4th largest worldwide

Turnover 2017 in Billion US-Dollar, TOP 10

Source: BPI (2018), based on World Review Analyst 2018 (IQVIA)
It accounts for 22% of the European pharmaceutical market ... and sales are on a high level.

Turnover in % (2018), EU-28

Pharmaceutical expenditure in Germany (in Billion €)

Sources: BPI (2018), based on World Review Analyst 2018 (IQVIA) and Statistisches Bundesamt 2017
The German health insurers have different instruments of pharmaceutical budget impact control in outpatient setting

- **New patented products**
  - Price negotiated with payers (GKV-SV) based on early benefit assessment (AMNOG)

- **„Old“ patented products*”
  - Price set by pharmaceutical company
  - Price freeze and mandatory discounts
  - In case of new indication: early benefit assessment possible („Kann-Regelung“)

- **Generic Products**
  - Reference pricing
  - Price freeze and mandatory discounts

- **OTC products**
  - Price set by pharmaceutical company
  - No reimbursement by SHI (beside exception list)

* launched before 2011
GKV-SV – National Association of Statutory Health Insurance Funds, SHI – statutory health insurance
Source: Ecker + Ecker GmbH
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How to find the best reimbursement strategy ?!
Healthcare in Germany is dominated by a system of statutory health insurers (SHI)

Expenditure on health in Germany 2017 (in %)

- SHI 57%
- PHI 8%
- private health insurers
- others 35%

• public budget
• care insurance
• pension insurance
• accident insurance
• employer
• private

PHI – private health insurers
Source: Statistisches Bundesamt (2019)
There is a trend to limit reimbursement of pharmaceuticals and medical devices

Last decade milestones

1989: Reference price system

1992: Doctors budget for prescription

2003: Change in reimbursement of inpatient treatment to flat-rate payment system (DRGs)

2004: Independent, evidence-based reports e.g. on drugs, non-drug interventions, diagnostic tests and screening tests (IQWiG)

2011: Early benefit assessment (outpatient) – (all new Rx-drugs)

2012: Benefit assessment of medical devices and drugs (inpatient)

2013: Early benefit assessment (outpatient) – (pharmaceuticals in market “Bestandsmarkt”)

2014: End of early benefit assessment (outpatient) - (pharmaceuticals in market “Bestandsmarkt”)

2016: Assessment of medical products of high risk classes – (inpatient)

2017: Early benefit assessment (inpatient) – (pharmaceuticals used in hospitals only)

DRG – diagnosis related groups, Rx - only available by prescription
Source: Ecker + Ecker GmbH
There is a handful of key institutions which define reimbursement for health care in Germany:

- **G-BA, IQWIG, GKV-Spitzenverband, DIMDI, InEK and PKV-Verband**

<table>
<thead>
<tr>
<th>Institution</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Federal Joint Committee</strong></td>
<td>- Decides on coverage and reimbursement of most health care services in Germany (SHI only)&lt;br&gt;- Decides on early benefit assessment of innovative pharmaceuticals</td>
</tr>
<tr>
<td><strong>Institute for Quality and Efficiency in Health Care</strong></td>
<td>- Assesses the medical and economical advantages and disadvantages of pharmaceuticals on behalf of G-BA (e.g. benefit dossiers)</td>
</tr>
<tr>
<td><strong>National Association of SHI Funds</strong></td>
<td>- Price negotiations after early benefit assessment&lt;br&gt;- Decides about pharmaceutical reference prices and maximum amounts</td>
</tr>
<tr>
<td><strong>German Institute of Medical Documentation and Information</strong></td>
<td>- Cataloguing institute (e.g. ICD and OPS)&lt;br&gt;- HTA</td>
</tr>
<tr>
<td><strong>Institute for the Hospital Remuneration System</strong></td>
<td>- Implementation, further development and maintenance of the hospital payment system (DRGs)</td>
</tr>
<tr>
<td><strong>Private Health Insurance Association</strong></td>
<td>- Effective lobbying (PHI only)&lt;br&gt;- Contract negotiations</td>
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</tbody>
</table>

*ICD – international classification of diseases, OPS – German procedure classification, HTA – health technology assessment*  
*Source: Ecker + Ecker GmbH*
Every sector and payer has its own reimbursement logic

Scheme of health care sector, market segments and payment

<table>
<thead>
<tr>
<th>Sector</th>
<th>Payer</th>
<th>outpatient</th>
<th>inpatient</th>
<th>other contractual arrangements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Statutory health insurance (SHI)</td>
<td>• Fee for service (GOÄ)</td>
<td>• Flat-rate payment system (DRG)</td>
<td>• § 63 SGB V “Pilot projects”</td>
<td></td>
</tr>
<tr>
<td>Private health insurance (PHI)</td>
<td>• Fee for service (GOÄ)</td>
<td>• Flat-rate payment system (DRG)</td>
<td>• § 116b SGB V “Ambulante spezialfachärztliche Versorgung”</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>• Fee for additional services (GOÄ)</td>
<td>• § 130a Abs. 8 SGB V “Rabattverträge”</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>• § 137e SGB V “Conditional reimbursement for medical devices”</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>• § 140a SGB V “Besondere Versorgung”</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>• Agreement with association of PHI</td>
<td></td>
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</tbody>
</table>
Outpatient reimbursement is based on a fee for service system

Outpatient

SHI: “Einheitlicher Bewertungsmaßstab“ (EBM)

• EBM is the Uniform Value Scale of the SHI for the payment of medical services
• EBM is regulated by German Social Code, Book V (SGB V) and the catalogue „EBM“ in its current version
  - Contains the catalogue of services, point value per service and time needed per service
  - Special chapter for each group of doctors

PHI: “Gebührenordnung für Ärzte“ (GOÄ)

• In Germany, doctors are not allowed to set their own prices, they have to charge in accordance with the German Medical Fee Schedule (GOÄ)
• In the GOÄ, nearly every medical service has a special number of points
• The monetary conversion factor is 0.0582873 per point

Most prescriptions are issued for outpatients, so EBM and GOÄ have an influence on prescription behaviour.
German hospital reimbursement is based on a flat-rate payment system

Inpatient

- The DRG system classifies patients into groups based on diagnosis, age, complications etc. and is mandatory for all hospitals
- For each group a flat-rate payment is defined
- There are additional payments on top of DRGs called “Zusatzentgelt“ (ZE) (e.g. dialysis and use of certain pharmaceuticals)
- In 2019, there are 1,318 different DRG codes and 214 ZE
- Reimbursement system is updated every year

Inpatient pharmaceutical pricing is nearly non-regulated but….

- no formal price regulation, but the hospital has to cover its pharmaceutical cost with the fixed reimbursement per case (with few exceptions)
- selling pharmaceuticals to hospitals for inpatient use requires a business case to buyer
- only 11% of all spendings for pharmaceuticals are in inpatient sector, but if a patient has been successfully treated with one medication, his willingness to switch is low
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Reimbursement of innovative drugs

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How to find the best reimbursement strategy ?!
Reimbursement of innovative drugs works by early benefit assessment

Legal details of benefit assessment were defined in 2011

- Mandatory for all new pharmaceuticals (German market entry after 01.01.2011)
- „New pharmaceutical“ is defined as new active substance with existing data exclusivity
- Pharmaceutical company has to prove additional benefit (dossier needed)
- Additional benefit is assessed by IQWiG and proven by G-BA
- Price negotiation depends on the extent of additional benefit proven

Note:

- Abbreviated assessment for orphan drugs
- Also assessment of drugs used only for inpatients (since 2017)
Early benefit assessment according to AMNOG follows clear rules

Main steps

- Overall process of benefit assessment and price negotiation takes about 12 months – plus about 12 months of preparation
- Pharmaceutical company can apply for new assessment after 12 months

* If price negotiation fails, the arbitration board makes price decision.

Sources: SGB V, Verfahrensordnung G-BA and Rahmenvereinbarung zu § 130b Abs. 9 SGB V
Basis of an early benefit assessment is the manufacturer’s dossier

Manufacturers submit dossier to the Joint Federal Committee electronically.

- G-BA template for assessment dossier has unfilled 122 pages, filled up to 1000 pages!
- The dossier must be submitted at the time when a drug is first brought into German market and has to contain information on:
  1. Authorized application areas
  2. Medical benefit
  3. Medical additional benefit compared to the appropriate comparative therapy
  4. Number of patients and patient groups for which a therapeutically significant additional benefit exists
  5. Therapy costs for the SHI
  6. Requirements for a quality-assured application

The burden of proof lies completely on the pharmaceutical company

Sources: § 35a SGB V and Ecker + Ecker GmbH
The two most critical aspects of benefit assessment can be discussed with G-BA in advance

Scientific advice

<table>
<thead>
<tr>
<th>Slicing of indication: not formalized, but 5 criteria used so far</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Treatment scheme</td>
</tr>
<tr>
<td>• Naive vs. pretreated patients</td>
</tr>
<tr>
<td>• Mono vs. combination therapy</td>
</tr>
<tr>
<td>• Label comparator</td>
</tr>
<tr>
<td>• Enumeration in section 4.1 SmPC</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Treatment comparator: 4 main criteria to be met</th>
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</thead>
<tbody>
<tr>
<td>• Approved in the relevant indication(s)</td>
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<tr>
<td>• Reimbursable by SHI</td>
</tr>
<tr>
<td>• Adequate therapy according to medical standards</td>
</tr>
<tr>
<td>• Therapy attributed additional benefit to via AMNOG</td>
</tr>
</tbody>
</table>
Every decision on additional benefit is made in two dimensions

Dimension of decision-making

- Major additional benefit
  “erheblicher Zusatznutzen”

- Considerable additional benefit
  “beträchtlicher Zusatznutzen”

- Minor additional benefit
  “geringer Zusatznutzen”

- Non-quantifiable additional benefit
  “Zusatznutzen nicht quantifizierbar”

- No additional benefit proved
  “Kein Zusatznutzen belegt”

- Less benefit than comparative therapy
  “Nutzen geringer als der Nutzen der zVT”

Strength of additional benefit vs. Quality of Evidence

- Extent of additional benefit
- Hint
  „Anhaltspunkt“

- Indication
  „Hinweis“

- Proof
  „Beleg“

Sources: Verfahrensordnung G-BA and Ecker + Ecker GmbH

zVT: Zweckmäßige Vergleichstherapie (engl.: appropriate comparator)
Effective reimbursement follows benefit assessment

Additional benefit and reimbursement

- **Scenario A**: Additional benefit - Drugs with/without additional benefit in comparison to appropriate comparator therapy
- **Scenario B**: Reference-priced group - Drugs within or not within a reference-priced group
- **Scenario C**: Reimbursement higher than price of appropriate comparator therapy

Reference price according to § 35 SGB V

Reimbursement up to price of appropriate comparator therapy

Sources: Rahmenvereinbarung zu § 130b Abs. 9 SGB V and Ecker + Ecker GmbH
Prices and volumes are defined during negotiation with GKV-Spitzenverband

Details on reimbursement

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**Negotiation details**

- Price negotiation with GKV-Spitzenverband can not be stopped (opt out only in the first 4 weeks)
- Negotiation is based on dossier, G-BA decision and “real-world data”
- Company has to submit the following data: treatment cost, expected volumes for their own product and relevant competitors (not only comparator)
- Company has to submit data on effective prices for their product in other European countries

**Rebate details**

**If no inclusion in FRP group:**
- Rebate will be negotiated
- Launch list price (AVP) is unchanged

*Rebate level will depend on benefit evaluation:*
- If additional benefit, then negotiations about mark up on appropriate comparators
- If no additional benefit, the net price to sick funds should not be higher than cost of comparative therapy

**If no agreement:**
- Rebate set by arbitration board

**Outcome:**
- Negotiation is on price and volumes

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FRP – Fixed reference price, AVP – pharmacy retail price
Sources: Rahmenvereinbarung zu § 130b Abs. 9 SGB V and Ecker + Ecker GmbH
Benefit assessment has wider implications on German pricing, marketing and sales strategy

<table>
<thead>
<tr>
<th>Implications</th>
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</thead>
<tbody>
<tr>
<td><strong>Implication 1</strong></td>
</tr>
<tr>
<td>• Benefit assessment produces a clear statement by G-BA and IQWIG on additional benefit to comparator (available also in English). This statement will be actively used in the marketplace.</td>
</tr>
<tr>
<td><strong>Implication 2</strong></td>
</tr>
<tr>
<td>• G-BA has defined a new health standard for health economic analysis and definition of prices.</td>
</tr>
<tr>
<td><strong>Implication 3</strong></td>
</tr>
<tr>
<td>• In negotiation with SHI – group price and volume is fixed maybe at competitors’ expense.</td>
</tr>
<tr>
<td><strong>Implication 4</strong></td>
</tr>
<tr>
<td>• Prescriber has to navigate between G-BA’s decision and existing contracts with SHI.</td>
</tr>
</tbody>
</table>

Source: Ecker + Ecker GmbH
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How to find the best reimbursement strategy ?!
Reimbursement of innovative medical devices is possible through different applications

- Medical device medically necessary according to § 29 AM-RL (CE certified)
  - outpatient: Reimbursement by existing EBM-code
    - Application for Anl. V AM-RL
  - inpatient: Reimbursement by existing DRG/ZE-code
    - Application for NUB
      - high-risk class

- Medical device as part of method (Untersuchungs- oder Behandlungsmethode)
  - Method covered by existing EBM-code?
    - yes: Reimbursement by existing EBM-code
      - Process under § 135 SGB V
    - no: Method covered by existing DRG/ZE-code?
      - yes: Reimbursement by existing DRG/ZE-code
        - Process under § 137e SGB V
      - no: Process under § 137c SGB V

*New code depending on outpatient (EBM-code) or inpatient care (DRG/ZE-code or NUB fee).
EBM: Einheitlicher Bewertungsmaßstab; ZE: Zusatzentgelt; NUB: Neue Untersuchungs- und Behandlungsmethoden; SGB V: fünftes Sozialgesetzbuch, AM-RL Arzneimittel-Richtlinie
Sources: G-BA, Bundesverband Medizintechnologie e. V., and Ecker + Ecker GmbH
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How to find the best reimbursement strategy ?!
Check reimbursement situation for your innovative products and define strategy

Key questions

### Relevant Questions

<table>
<thead>
<tr>
<th>Check</th>
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<tbody>
<tr>
<td>• Are there similar products in the market?</td>
</tr>
<tr>
<td>• What is the relevant reimbursement environment?</td>
</tr>
<tr>
<td>• Is it a drug (early benefit assessment) or a medical device (OPS, ICD, ZE)?</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Evaluate</th>
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<tbody>
<tr>
<td>• Which evidence is available to support the product value?</td>
</tr>
<tr>
<td>• Which is the adequate study design?</td>
</tr>
<tr>
<td>• Where to use the product: in- or outpatient?</td>
</tr>
<tr>
<td>• Is the product covered by guidelines?</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Define</th>
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<tbody>
<tr>
<td>• Which is the clinical product value (German market)?</td>
</tr>
<tr>
<td>• Which is the economic value for the payer and the patient?</td>
</tr>
<tr>
<td>• How can medical and economic advantages be quantified for the price negotiations?</td>
</tr>
<tr>
<td>• Which is the right activity sequence in the reimbursement process?</td>
</tr>
<tr>
<td>• How to communicate the value story?</td>
</tr>
</tbody>
</table>

Act!
Thank your for your attention!