Germany’s healthcare market
Market Participants

Health Insurance
State insurance 109 (85%)
Private insurance 44 (11%)

Hospitals 1 948
Nursing homes 13 596
Home-care nursing 13 323
“Sanitätshäuser“ 7 500
Pharmacies 18 880
Physicians, Physiotherapists ..
Germany’s Reimbursement Process

1. Application
2. Approval
3. Product listing
4. Review
5. Contract
6. Supply
7. Healthcare Provider
8. 109 Health Insurances
9. Hilfsmittelverzeichnis (HMV)
### HMV/PHMV - Database

<table>
<thead>
<tr>
<th>Group</th>
<th>Product types</th>
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<tbody>
<tr>
<td>01</td>
<td>Suction devices</td>
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<td>Positioning support</td>
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<td>Measurement device for bodily functions</td>
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<td>Aids for independent living/mobility</td>
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<td>Aids for pain relief</td>
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<td>One-time-use product waste</td>
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<td>99</td>
<td>Various</td>
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</tbody>
</table>

**42 product groups**
**more than 600 subgroups**
**More than 1800 product types**
**Approx. 30 000 products**

**Online information:**
https://hilfsmittel.gkv-spitzenverband.de/home.action
https://www.rehadat-gkv.de/

Products for care "Pflegehilfsmittelverzeichnis"
10-digit reimbursement code

- **Group**: XX
  - Mobility
  - Braces
  - Respitaroy
  - ...

- **Application**: XX
  - Indoors
  - Outdoors
  - Hand
  - Body
  - ...

- **Subgroup**: XX
  - Functionality
  - Weight
  - Powered
  - ...

- **Type**: X
  - Design
  - Material
  - Other
  - features
  - ...

- **Product**: XXX
  - Specific
Reimbursable Products (SGB V)

“...only products with one of the functionalities below can be listed”

- Necessary for the medical treatment success
- Prevent an imminent disability
- Compensate for disability
Requirements for HMV-code

- I. Functionality
- II. Safety
- III. Special
  - III.1 Indication and application
  - III.2 Life time / durability
  - III.3 Re-use
- IV. Medical benefits
- V. User’s Instructions
- VI. Additional

Statements and proofs
- Declaration of Conformity
- Medical case report
- Product test report
- Adjustments-statement

MDR 2017/745/EU  
(MDD 93/42/EEC)
Application process

1. Submission file
2. Forwarding
3. Recommendation
4. File review and evaluation by internal and external experts
5. Additional evaluation, e.g., check for legal status of reimbursement
6. Publish in HMV/PHMVF
7. 3-4 months (best case scenario)

Hilfsmittelverzeichnis (HMV/PHMVF)
Reimbursement amounts?

**Fixed amount only for special products**

**Basically, contracts about product types and services**

**Contract partners:**
Health insurance and healthcare provider

**Clearing center as optional service provider**

Barmer, TK, KKH, AOK (regional), IKK, DAK, BKK etc.

109 Health-Insurances

Contract

Optadata, AZH, acriba, optica etc.

Clearing center (service provider)

Sanitätshäuser, pharmacies, audiologists, opticians, care services orthopadic shoemaker etc.

70,000 Healthcare-Provider

Contract

Contract

Contract
HMV Facts

- CE mark is mandatory: MDR 2017/745/EU
- Additional Requirements: German Social Law (SGB V)
- Further marketing is necessary
- Opens door to market participants
- Only manufacturers are registered
- Straightforward reimbursement
### Heil- und Hilfsmittelversorgungsgesetz – (HHVG)
(Healing- and Technical-Aid Supply Law)

<table>
<thead>
<tr>
<th>Frequent review</th>
<th>Database update</th>
<th>Delete „old“ products</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stricter requirements</td>
<td>More patients for case studies</td>
<td>Limited to specific indications</td>
</tr>
<tr>
<td>New rules</td>
<td>Registration fees are possible</td>
<td>Report: product changes</td>
</tr>
</tbody>
</table>
Thank you very much!

Contact:
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