How Does Europe Do It?
Balancing Adoption and Affordability of Medical Devices

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Why balancing the adoption and affordability?

- Evidence suggests that health interventions are associated with dramatic improvements in life expectancy (Hunink 1997, Cutler and McClellan 2001, Cutler 2007)

- Technological change has accounted for a large part of health care expenditures
- Spending on pharmaceuticals and medical devices seems to be a stronger driver of expenditures than demographic change (Busse et al. 2007)

- Regulations for pharmaceuticals have been subject to numerous studies, whereas the regulation of medical devices has rarely been analyzed
## Expenditures on medical devices

<table>
<thead>
<tr>
<th>Country</th>
<th>THE Billion €</th>
<th>THE % GDP</th>
<th>EMD Billion €</th>
<th>EMD % THE</th>
<th>EMD % GDP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Europe Total/ Average</td>
<td>1034.4</td>
<td>8.7%</td>
<td>63.6</td>
<td>6.3%</td>
<td>0.5%</td>
</tr>
<tr>
<td>Germany</td>
<td>232.2</td>
<td>10.3%</td>
<td>20.0</td>
<td>8.6%</td>
<td>0.9%</td>
</tr>
<tr>
<td>France</td>
<td>172.6</td>
<td>10.5%</td>
<td>10.0</td>
<td>5.8%</td>
<td>0.6%</td>
</tr>
<tr>
<td>Italy</td>
<td>126.0</td>
<td>8.8%</td>
<td>7.0</td>
<td>5.6%</td>
<td>0.5%</td>
</tr>
<tr>
<td>UK</td>
<td>148.3</td>
<td>8.4%</td>
<td>6.7</td>
<td>4.5%</td>
<td>0.4%</td>
</tr>
<tr>
<td>Spain</td>
<td>67.3</td>
<td>7.4%</td>
<td>5.5</td>
<td>8.2%</td>
<td>0.6%</td>
</tr>
<tr>
<td>Poland</td>
<td>12.6</td>
<td>6.5%</td>
<td>0.9</td>
<td>6.9%</td>
<td>0.4%</td>
</tr>
<tr>
<td>USA</td>
<td>1440.5</td>
<td>15.3%</td>
<td>79.4</td>
<td>5.5%</td>
<td>0.8%</td>
</tr>
</tbody>
</table>

Source: based on Eucomed 2007
# Licensing decision in the EU

<table>
<thead>
<tr>
<th>Licensing regulation</th>
<th>EU regulation (medical devices directives), transposed into national law</th>
</tr>
</thead>
<tbody>
<tr>
<td>Actual licensing decision on a certain medical device</td>
<td>Notified bodies in 27 member states (but decision is also valid in all other 26 countries) – decision depends on safety concerns</td>
</tr>
</tbody>
</table>

- Coverage decision
- Reimbursement decision
Coverage decision in the EU

Licensing decision

Coverage (public benefit basket)
- EU member states, usually at national level, either through government or through self-governing bodies

Reimbursement decision
Reimbursement decision in the EU

Licensing decision

Coverage decision

Reimbursement rates

National or sub-national, either through government or through self-governing bodies
Coverage policy in Germany

Decision makers on coverage policy

• **The Federal Joint Committee**
  – consists of representatives of providers and payers
  – is Responsible for the DRG system
  – defines the benefit catalogue for outpatient benefits

• **The Institute for Quality and Efficiency:**
  – acts as an advisory body to the Federal Joint Committee

• **The Federal Association of Sickness Funds:**
  – defines a positive list for medical aids
## Reimbursement regulations in Germany

<table>
<thead>
<tr>
<th>Category of medical devices</th>
<th>Reimbursement in Germany</th>
</tr>
</thead>
</table>
| **Cat I - Medical aids:**  | For outpatient care: reference prices, public tenders  
                          | For inpatient care: Included in case fees |
| e.g. incontinence pads, negative pressure therapy | |
| **Cat II - Implants etc.:** | Included in case fees, additional payments for certain technologies |
| e.g. knee endoprostheses, implantable cardioverter defibrillators, coronary stents | |
| **Cat III - Technical equipment for professionals:** | Short-life products: Included in case fees  
                          | Long-life products: Funded as capital by the federal states |
| e.g. laparoscope | |
Reference prices for Incontinence Pads

- There are reference prices (RPs) for Incontinence pads
- RPs serve as a reimbursement limit
- Products are grouped in homogeneous classes; for each group, reference prices are set
## Reference prices for Incontinence Pads

<table>
<thead>
<tr>
<th>Number of position</th>
<th>Term</th>
<th>Reference price [€] [each]</th>
</tr>
</thead>
<tbody>
<tr>
<td>15.25.01</td>
<td>absorptive incontinence pad</td>
<td></td>
</tr>
<tr>
<td>15.25.01.0</td>
<td>Anatomical formed incontinence pad, normal absorptive capacity, size 1</td>
<td>0.29</td>
</tr>
<tr>
<td>15.25.01.1</td>
<td>dito., size 2</td>
<td>0.35</td>
</tr>
<tr>
<td>15.25.01.2</td>
<td>dito., size 3</td>
<td>0.43</td>
</tr>
<tr>
<td>15.25.01.3</td>
<td>rectangular formed incontinence pad, size 1</td>
<td>0.19</td>
</tr>
<tr>
<td>15.25.01.4</td>
<td>rectangular formed incontinence pad, size 2</td>
<td>0.23</td>
</tr>
<tr>
<td>15.25.01.5</td>
<td>incontinence pad for urinary incontinence</td>
<td>0.21</td>
</tr>
<tr>
<td>15.25.03</td>
<td>absorptive incontinence pants</td>
<td></td>
</tr>
<tr>
<td>15.25.03.0</td>
<td>incontinence pants, size 1</td>
<td>0.49</td>
</tr>
<tr>
<td>15.25.03.1</td>
<td>incontinence pants, size 2</td>
<td>0.51</td>
</tr>
<tr>
<td>15.25.03.2</td>
<td>incontinence pants, size 3</td>
<td>0.69</td>
</tr>
</tbody>
</table>

(Version: Bundesanzeiger No. 170, 11.09.2007)
Reference prices for Incontinence Pads

- There are reference prices (RPs) for Incontinence pads
- RPs serve as a reimbursement limit
- Products are grouped in homogeneous classes; for each group, reference prices are set
- Manufacturers have a voice in this process
- Patients have to make co-payments
- Patients are free to choose any product with a price higher than the RP if they are willing to pay the difference between the actual selling price and the RP
Medical Aids: Expenditures from public sources under a reference price regime

- Incontinence aids
- All non-reference-price categories
- Hearing aids
- All reference-price categories (excl. visual aids)
- Ostomy products
- Arch support
- Compression therapy
Implants and the G-DRG-System

- In general, all costs for implants are included in the relevant DRGs.
- There are additional payments for certain implants.
- This includes implants that are not „sufficiently reimbursed“ by the DRG system.
- These additional payments may be defined either
  - On national level (national uniform additional payments)
  - By direct negotiations between hospitals and sickness funds.
Knee endoprostheses, ICDs and stents in the G-DRG-Systen

Figure: Reimbursement Components of Inpatient Care in Germany (Schreyögg J, Tiemann O, Busse R (2006) Cost accounting to determine prices: How well do prices reflect costs in the German DRG-system? Health Care Manage Sci 9:269-279. With own adaptations and extensions)
### Market interventions in the German medical devices market

Spending = Price x Volume

- Co-payments
- Reference pricing
- Framework set by reimbursement tariffs

- Clinical guidelines
- Framework set by benefit catalogues

- Spending caps (wound care products)
- Public tenders
• Most market interventions are intended to reduce spending
  – Spending caps
  – Public tenders
  – DRG-tariffs

• What about balancing?
  – Reference prices
  – Annual revision of the DRG-tariffs and the DRG-Groups
  – Additional payments in the DRG-System

• Measures intended for the diffusion of technologies:
  – Additional payments for new technologies
    => Further research on the practical relevance is needed