Biopharmaceutical Industry Principles and Perspectives on HTA

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Some Common Challenges

- Growing and aging populations
- Rising rates of chronic disease
- Increased demand for health care
- Difficult health care choices
Regulatory vs. Reimbursement Decisions

Regulatory approval focuses on three primary criteria while reimbursement processes and standards vary significantly.

Regulatory Approval:
- Safety
- Efficacy
- Quality

Reimbursement Decisions:
- Impact
- Innovation
- Affordability
- Patients
- Quality-of-Life
- Benefit
- Budget
- Clinical
- Access
- Benefit
- Cost-Effectiveness
- Unmet
- Societal
- Endpoints
- Surrogate
- Therapeutic
- Industry
- Outcomes
- Stakeholders
- Uncertainty
- Patients
- Need
- Added
- Reference
- Innovation
- Area
- Cost-Effectiveness
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Perspectives on Value

Innovative medicines deliver value in four interdependent areas

- Clinical Value
- Patient Value
- Health Care System Value
- Societal Value
Value Assessment Frameworks

- Added Clinical Benefit Assessment
- Cost-Effectiveness Analysis
- Multi-Criteria Decision Analysis

£/QALY
Key Attributes of Well-Functioning Systems

Transparency, flexibility, stakeholder engagement and patient access are key attributes of a well-functioning value assessment system.
Country System Strengths and Limitations

**Strengths**

<table>
<thead>
<tr>
<th>Country</th>
<th>Strengths</th>
</tr>
</thead>
</table>
| Australia | • Structured timelines  
• Transparent in decision rationale and publishes all decisions |
| Korea | • Transparent criteria for submission  
• Clinician and patient representation during assessment |
| England | • Transparent requirements and methodology  
• Good engagement of all stakeholders |
| France | • More transparent methodology of value assessment  
• Flexible in data considered  
• Industry engagement |
| Germany | • Higher reward for innovation  
• More transparent value assessment data requirements, methodology and timelines |

**Limitations**

<table>
<thead>
<tr>
<th>Country</th>
<th>Limitations</th>
</tr>
</thead>
</table>
| Australia | • Fundamental focus on cost containment  
• Insufficient opportunity for industry to address questions during assessment  
• Initial submission deferrals and rejections are common |
| Korea | • Fundamental focus on cost containment  
• Low ICER threshold and price controls limit patient access to innovative medicines |
| England | • Focus on QALYs and ICER ignores many aspects of a product’s value  
• Low ICER threshold limits patient access to innovative medicines, especially for oncology and rare diseases |
| France | • Lack of transparency in how assessment translates to price  
• Limited physician and patient input  
• Long timelines result in patient access delays |
| Germany | • Rigid data requirements  
• Lack of transparency in how assessment translates to price |

- **Australia**
- **Korea**
- **England**
- **France**
- **Germany**
### Country Differences in Access to New Medicines

<table>
<thead>
<tr>
<th>Country</th>
<th>Global New Medicines Available</th>
<th>Covered without Restrictions</th>
<th>Delay in Coverage from Global Launch</th>
</tr>
</thead>
<tbody>
<tr>
<td>US</td>
<td>88%</td>
<td>100%</td>
<td>2 Months</td>
</tr>
<tr>
<td>Germany</td>
<td>67%</td>
<td>100%</td>
<td>10 Months</td>
</tr>
<tr>
<td>Japan</td>
<td>53%</td>
<td>100%</td>
<td>16 Months</td>
</tr>
<tr>
<td>UK</td>
<td>60%</td>
<td>46%</td>
<td>20 Months</td>
</tr>
<tr>
<td>France</td>
<td>53%</td>
<td>56%</td>
<td>27 Months</td>
</tr>
<tr>
<td>Australia</td>
<td>36%</td>
<td>56%</td>
<td>32 Months</td>
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Value Assessment Principles

- Sound Process
- Patient-Centered Focus
- Reliable and Relevant Information
- Recognition of Progress and Innovation
- System-Wide Perspective
Thank You