

# HTA IN GERMANY: EVIDENCE REQUIREMENTS, THE ROLE OF BENEFIT/COST ASSESSMENT, FIRST EXPERIENCES AND CHALLENGES WITH THE GERMAN HEALTH BILL AMNOG

Anne Heyes, MBA  
European Head Market Access and Outcomes Strategy, RTI-HS

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For successful market access of a new product, manufacturer must meet P&R requirements of all markets



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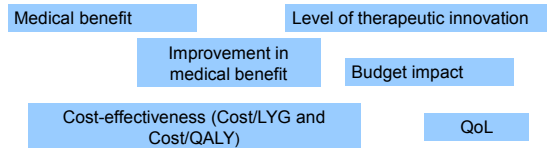
## Questions that payers will ask

- How should we use it ?**
  - Role, position in therapy?
  - Which patients?
  - When?
  - For how long?
- What does it cost? (Can we afford it?)**
  - Cost of Budget Impact?
- Is it good value for money?**
  - Cost Effectiveness?
- Does it improve the patients' health state?**
- What is the impact on Quality Of Life (QOL)**
  - Quality-adjusted life-years (QALYs) and QOL assessment?
- Is there a better use for our money?**
  - Resource allocation?

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## Some of the payer-relevant measures used in different markets



Considerations; Different methodological requirements, different comparators, different emphasis on cost-effectiveness etc.

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### Criteria used in global HTA

Criteria	Australia	Canada	France	Germany	Netherlands	Sweden	UK
Therapeutic benefit	•	•	•	•	•	•	•
Patient benefit	•	•	•	•	•	•	•
Cost-effectiveness	•	•		(•)	•	•	•
Budget impact	•	•	•	•	•		•
Pharmaceutical innovation		•	•		•		•
Availability of alternatives	•			•	•	•	•
Equity considerations		•				•	•
Public health impact		•	•				
Research & development	•						

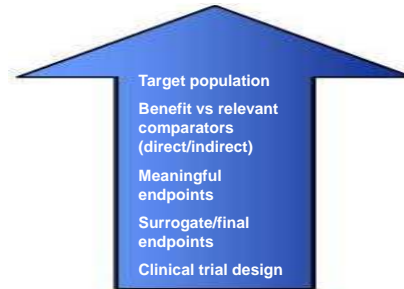
Source: Adapted from Zentner A, Valasco-Garrido M, Busse R. Methods for the comparative evaluation of pharmaceuticals. GMS Health Technol Assess. 2005;1:Doc09.

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### Each market requires a payer-resonant value story

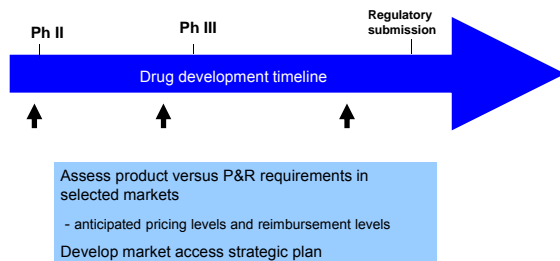


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### Manufacturer should monitor estimated success of market access for product during development



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### Develop integrated business decision framework

- Conduct feasibility/risk assessment on TPP or actual product profile
- Variety of methods:
  - Payer research
  - P&R assessment tool
    - Simple: MA checklist – identify specific risks
    - Comprehensive: model with payer-defined inputs and risk assessments
- Assess probability of success/market and use to define subsequent support activities inside and outside clinical programme

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## Conclusions

- Many different P&R requirements across markets
  - Evolution with time
- Plan market access strategy early
- Monitor