



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

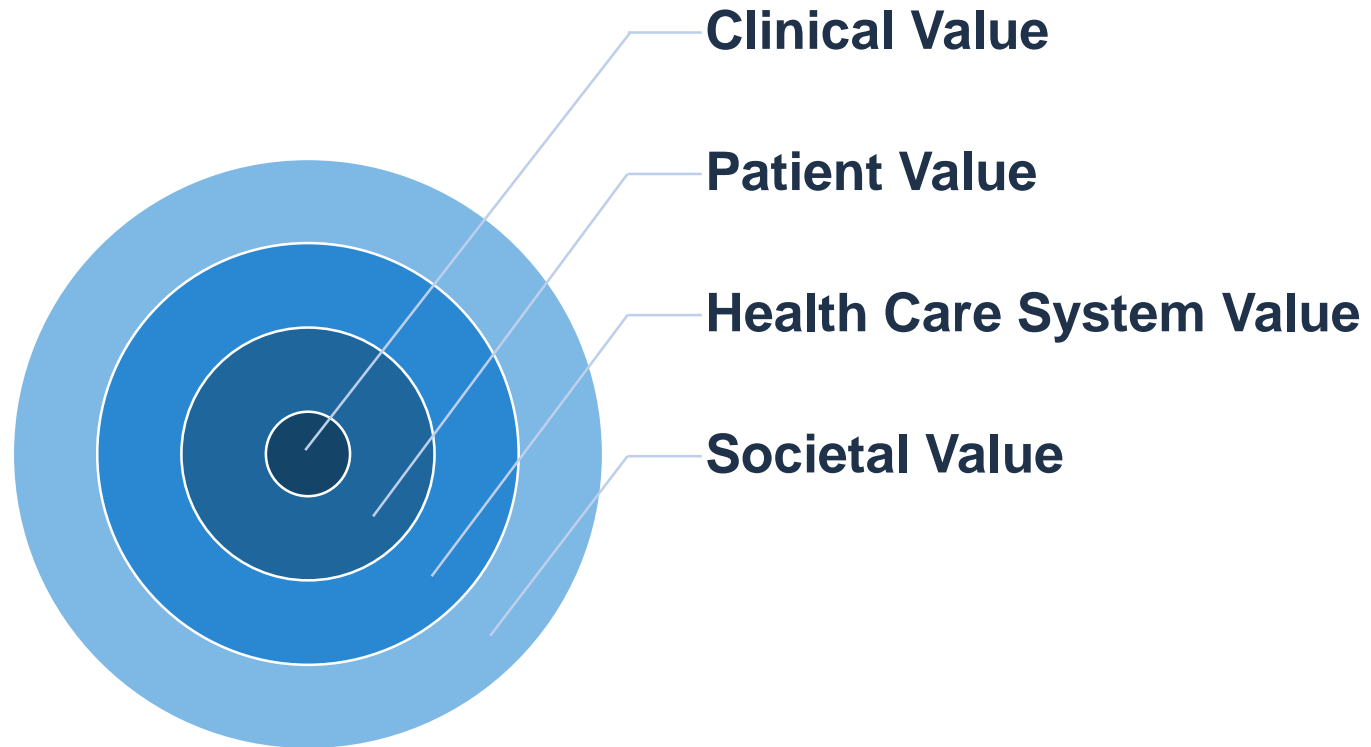
Safety
Efficacy
Quality

Reimbursement Decisions



Perspectives on Value

Innovative medicines deliver value in four interdependent areas

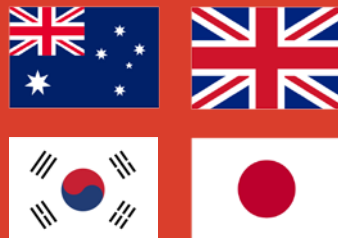


Value Assessment Frameworks

Added Clinical Benefit Assessment



Cost-Effectiveness Analysis



Multi-Criteria Decision Analysis



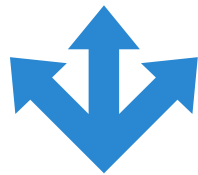
Key Attributes of Well-Functioning Systems

Transparency, flexibility, stakeholder engagement and patient access are key attributes of a well-functioning value assessment system

Transparency



Flexibility



Stakeholder Engagement



Patient Access



Country System Strengths and Limitations



Australia



Korea



England



France



Germany

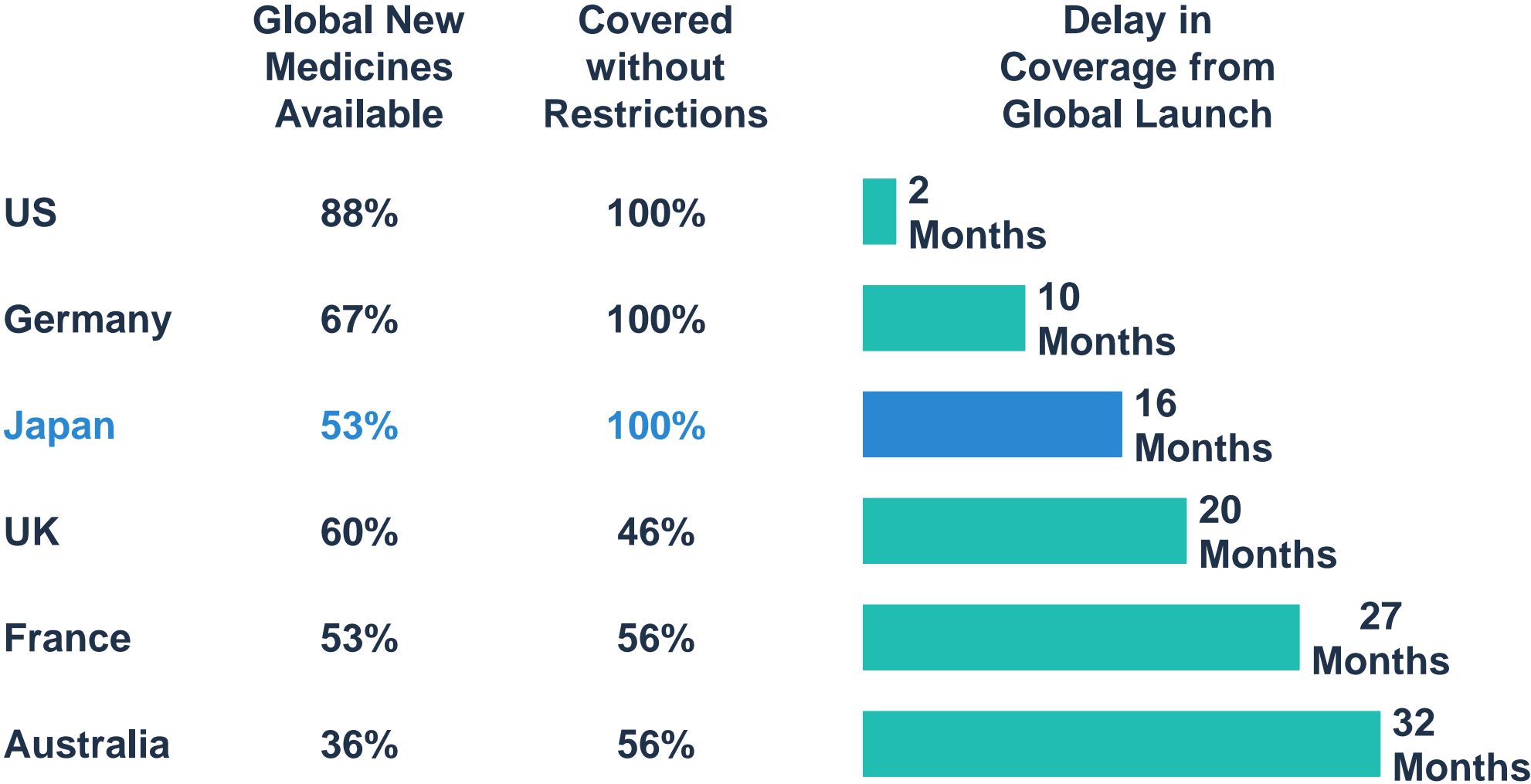
Strengths

- | | | | | |
|---|---|---|--|--|
| <ul style="list-style-type: none"> • Structured timelines • Transparent in decision rationale and publishes all decisions | <ul style="list-style-type: none"> • Transparent criteria for submission • Clinician and patient representation during assessment | <ul style="list-style-type: none"> • Transparent requirements and methodology • Good engagement of all stakeholders | <ul style="list-style-type: none"> • More transparent methodology of value assessment • Flexible in data considered • Industry engagement | <ul style="list-style-type: none"> • Higher reward for innovation • More transparent value assessment data requirements, methodology and timelines |
|---|---|---|--|--|

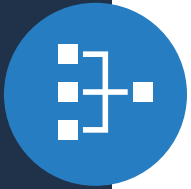
Limitations

- | | | | | |
|---|--|--|---|--|
| <ul style="list-style-type: none"> • Fundamental focus on cost containment • Insufficient opportunity for industry to address questions during assessment • Initial submission deferrals and rejections are common | <ul style="list-style-type: none"> • Fundamental focus on cost containment • Low ICER threshold and price controls limit patient access to innovative medicines • Lack of transparency and long timelines result in patient access delays | <ul style="list-style-type: none"> • 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 | <ul style="list-style-type: none"> • Lack of transparency in how assessment translates to price • Limited physician and patient input • Long timelines result in patient access delays | <ul style="list-style-type: none"> • Rigid data requirements • Lack of transparency in how assessment translates to price • Limited stakeholder involvement in comparator selection |
|---|--|--|---|--|

Country Differences in Access to New Medicines



Value Assessment Principles



Sound Process



Patient-Centered Focus



Reliable and Relevant Information



Recognition of Progress and Innovation



System-Wide Perspective



Thank You

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