Managed Entry Agreements for Medical Devices: Great Opportunity or Major Challenge?

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ISPOR Glasgow European Meeting
November 2017
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Disclaimers

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Todays Agenda: Risk Sharing Agreements

1. Does the concept of ‘risk sharing’ make sense in principle?

2. Are they more suited to some situations than in others?

3. What are the main practical challenges?

Do Risk Sharing Agreements make sense in Principle?

What does ‘Economic Evaluation’ Mean?

First, it deals with both inputs and outputs, sometimes called costs and consequences, of activities.

Few of us would be prepared to pay a specific price for a package whose contents are unknown.

Conversely, few of us would accept a package, even if its contents are known AND desired, until we knew the specific price.

In both cases, it is the linkage of costs and consequences which allows us to reach our decision.

Do Risk Sharing Agreements Make Sense in Principle?

Risk sharing is a way to **reduce the inherent uncertainty in decision making** based on economic evaluations. Risk sharing takes us **beyond the quantification of costs and consequences**, to the **implementation of effective policy and healthcare interventions**.

**National To Local: Risk Sharing Enables Economic Evaluation**

**Todays Agenda**

1. Does the concept of ‘risk sharing’ make sense in principle? **YES**

2. Are they more suited to some situations than in others?

3. What are the main practical challenges?
Risk Sharing Agreements: When are they appropriate?

Risk being shared: **Price (Value) Risk**
-Designed to impact ‘value’ via a change in price levels per product.

Risk being shared: **Uncertainty** Risk
-Designed to impact ‘value’ via a change in level of uncertainty on product adoption.

Typically for currently reimbursed products where ‘value’ has already been ‘assigned’.

For new products where ‘value’ is yet to be determined and risk is ‘uncertainty’.


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**Innovative pharma contracts: When do value-based arrangements work?**

By Arnab Chatterjee, Casey Dougan, BJ Tevelow, and Amir Zamani

Italy leads the development of publicly disclosed innovative contracts, with the United States following.

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Source: Richard Charter, Market Access & Pricing, Diabetes Care Europe
Risk Sharing Agreements: When are they appropriate?

Innovative pharma contracts: When do value-based arrangements work?

By Arnaub Chatterjee, Casey Dougan, BJ Tevelow, and Amir Zamani

1. The product (outcomes) is a priority for payers, with considerable value at stake.

2. Manufacturers need to differentiate their offerings against significant in-class competition. Diabetes and oncology are prime examples.

3. Manufacturers are challenged to guarantee value because medical benefit is longer term and unpredictable. Eg. Chronic illness.

EU MEAT Directive on Public Procurement

DIRECTIVE 2014/24/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 26 February 2014

on public procurement and repealing Directive 2004/18/EC

EU Directive on public procurement from 2014
The Procurement Model to Facilitate Dialogue

From categories to Criteria

Res tantum valet quantum vendi potest
Richard Charter, Market Access & Pricing, Diabetes Care Europe
Todays Agenda

1. Does the concept of ‘risk sharing’ make sense in principle? **YES**

2. Are they more suited to some situations than in others? **YES**

3. What are the main practical challenges?

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The Value Proposition: User Training & Skill
What are the Main Practical Challenges?

The 3 ‘T’s of Patient Access Agreements?

1. **Talent:** Both manufacturers and local payers will need to think more holistically about value in health, and how to measure this than is currently being done. **BEST PRACTICE:** MEAT procurement working group.

2. **Technical Criteria:** There needs to be 3 core components to be aligned around, with competencies and authority to agree on:
   i. Clinical Protocol with measurable patient outcomes
   ii. Internal AND external ‘business case’.
   iii. Clearly defined, and agreed to exit strategies from the agreement.

3. **Trust:** Are the exit strategies clearly articulated and how do BOTH sides live up to this expectation?

This requires a collaborative approach
Conclusions

1. Does the concept of ‘risk sharing’ make sense in principle?

YES

2. Are they more suited to some situations than in others?

YES

3. What are the main practical challenges?

TALENT

TECHNICAL

TRUST