

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

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Disclaimers

The views presented are that of the presenter and do not necessarily reflect those of the affiliated organisations or their subsidiaries.

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Today's 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?

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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.

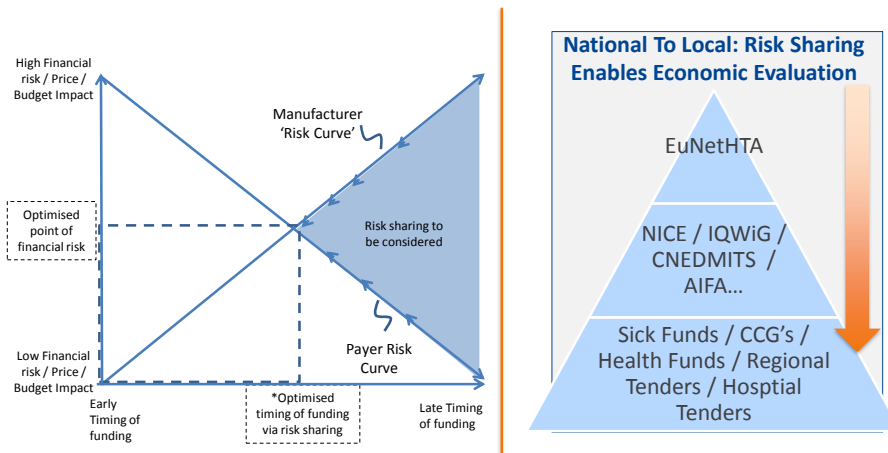
Conversely, few of us would accept a package, even if its contents are known AND desired, until we knew the specific price.

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

Source: Drummond M, Obrien B, Stoddart G & Torrance G. *Methods for the Economic Evaluation of Health Care Programmes*. Oxford Medical Publications, Second Edition. Page 8

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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**.

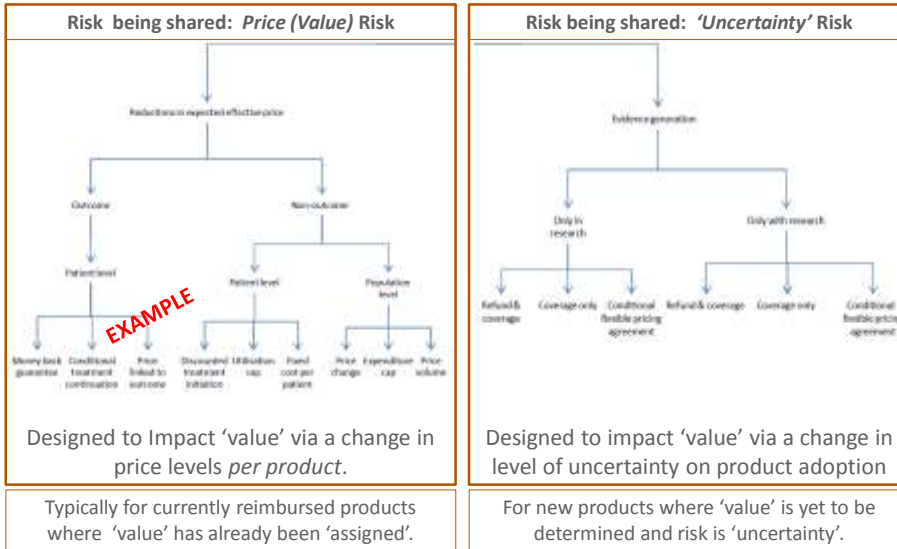
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Risk Sharing Agreements: When are they appropriate?



Source: Walker, Sculpher, Claxton, Palmer. Coverage with Evidence Development, Only in Research, risk sharing or patient access scheme? A Framework for Coverage Decisions. Value in Health, 2012.

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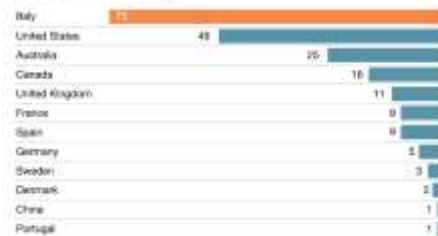
Risk Sharing Agreements: When are they appropriate?

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

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

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

Innovative contracts by country since 1994, number of public contracts executed



Source 1

Of the publicly disclosed innovative contracts analyzed, around half were in oncology and hematology.

Global innovative contracts by therapeutic area since 1994, number of public contracts executed



Source 2/Source 3: Source: McKinsey analysis

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Risk Sharing Agreements: When are they appropriate?

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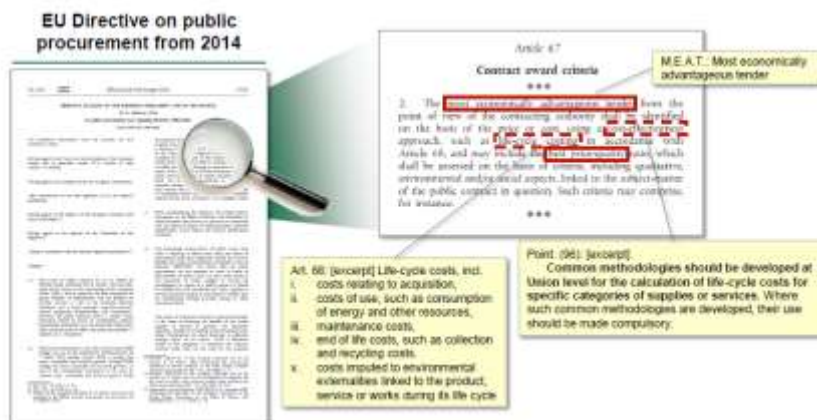
By Arnaub Chatterjee, Casey Dougan, BJ Tevelow, and Amir Zamani

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

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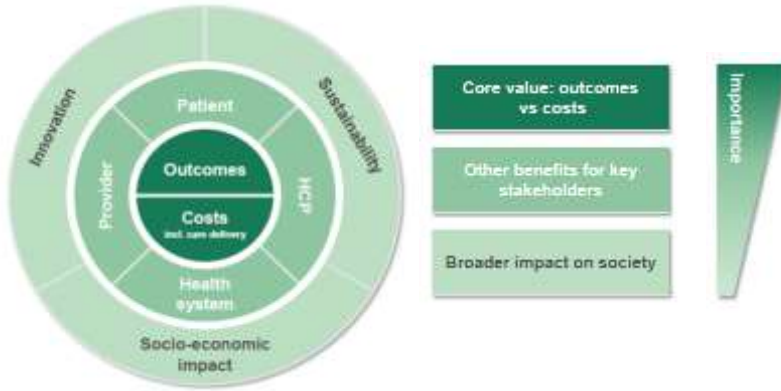
EU MEAT Directive on Public Procurement

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



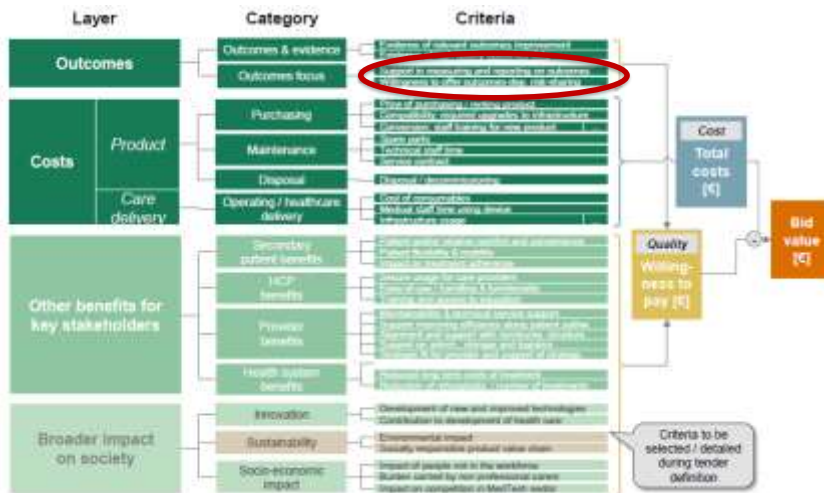
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The Procurement Model to Facilitate Dialogue



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From categories to Criteria



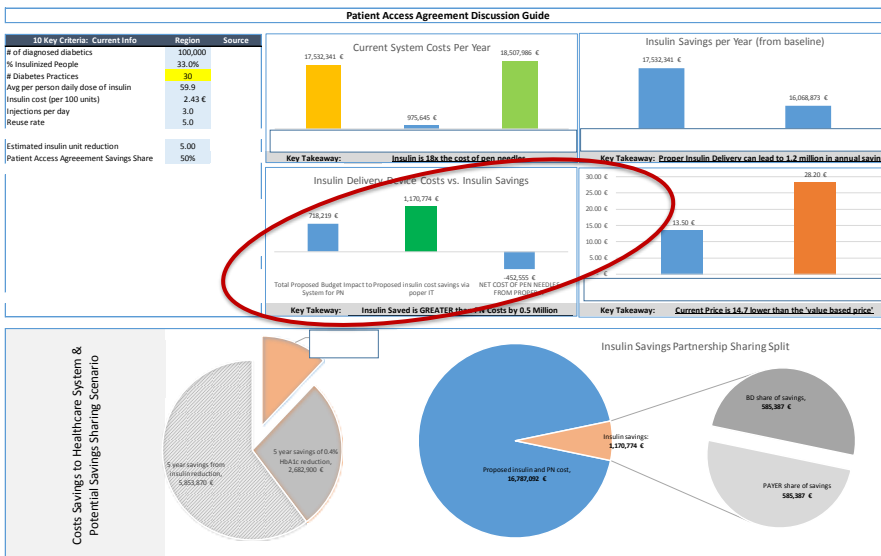
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Today's Agenda

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The Value Proposition: User Training & Skill



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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?

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This requires a collaborative approach

Define a common framework and practical tool to align all stakeholders on MEAT tendering



Make tendering
best practices the
common practice

Ensure best value
achieved for
patients, providers,
health systems and
society as a whole
for the money
invested

TO MAKE IT A REALITY !

PROVIDE THE TOOLS AND
ENSURE A LEGAL FRAMEWORK

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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**

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