HTAi Workshop: Risk Sharing Agreements— a company perspective

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Workshop Goals: risk sharing among manufacturers, regulators, payers

1) Share information on the drive for regulatory and payer focused risk sharing
2) Outline a range of payer-focused risk sharing models
3) Address barriers to risk sharing
4) Propose elements of model agreements

Pressure in the system driving change

Patient expectations

- Demand for timely access and emphasis on unmet need

Scientific challenge:

- Fragmentation of treatment populations
- Early disease interception
- Uncertainty around new science (e.g., biomarkers, etc.)

Healthcare systems and innovative companies are under pressure

- Affordability crisis
- Sustainability of drug development called into question by increasing requirements and spiraling costs

"The safest drug that no one can afford or that arrives too late is of no benefit to a patient." (M. Skinner, Plenary HTAi Annual Conference 2014)

Objective of risk sharing agreements

Bridge the divide between perceptions of value

- ✓ Alleviate concerns about financial or clinical uncertainty
- ✓ Improve quality of care and patient access (for the right patients)
- ✓ Learn more about use in real-world setting

HTA and Regulatory Early Scientific Advice

CHALLENGES

For all stakeholders

- Jurisdictional and contextual differences
- Differences in remits and purposes
- How to resolve conflict

For industry

- Concerns about sharing proprietary information
- How to satisfy diverse requirements
- Concerns about increasing evidentiary burden

For regulatory / HTA / coverage bodies

- Resource demands
- Legal constraints
- Working with different stakeholders

BENEFITS

For all stakeholders

- Better awareness roles and remits
- Opportunity to build trust and understanding
- Efficiency gains

For industry

- Facilitates drug development planning
- Greater understanding of differences in requirements
- Coordination across multiple markets

For regulatory / HTA / coverage bodies

- Improved coordination of evidentiary expectations
- Opportunity to clarify why requirements may be different
- *Potential* reduction of advice duplication

Source: Frønsdal et al (2012) IJTAHC: 28: 374-381

Improving advice processes

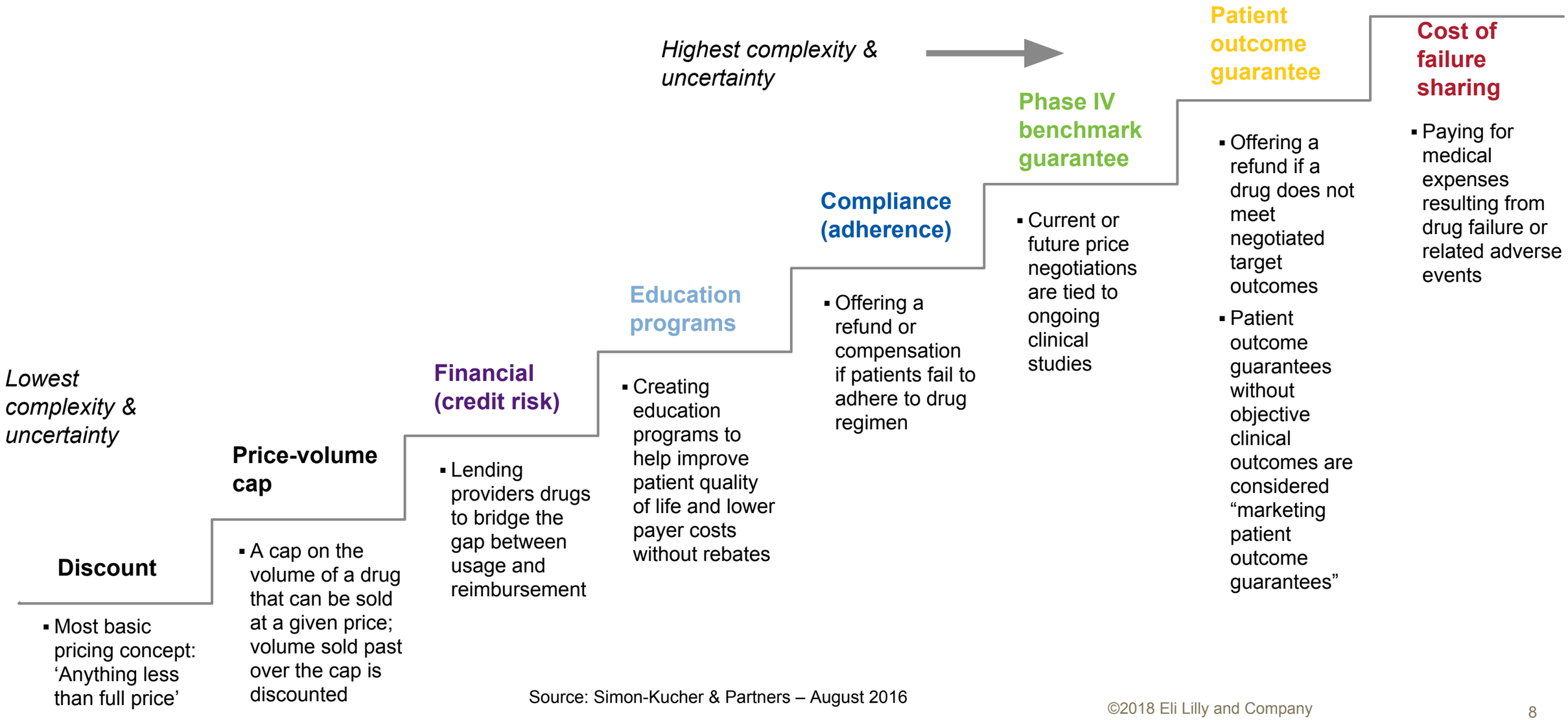
At the level of individual initiatives	Feedback from all stakeholders Advantage: timely and detailed Needs to be: transparent, publically available Allows the individual process to evolve and improve
Comparison between initiatives	Allows identification of strengths and weaknesses Facilitates improvement (internal / external) Helps guide development of new processes HTAi Interest Sub Group

Adaptive Pathways: a novel approach

- Require change across **entire lifecycle** of the drug
- Require **all stakeholders to provide input** and make trade offs
- **Prospectively planned** and flexible (one size does not fit all)
- **"…development programme is (re)structured to allow for early approval *and coverage* of a new compound for a limited population…based often on smaller initial clinical studies"**[1]
- **Iterative phases of evidence gathering** to reduce uncertainties
- Approved indications, coverage and therapeutic value **re-evaluated** as new efficacy, safety, effectiveness data is developed
- Treatment **populations can be broadened or restricted** based on the revaluations.

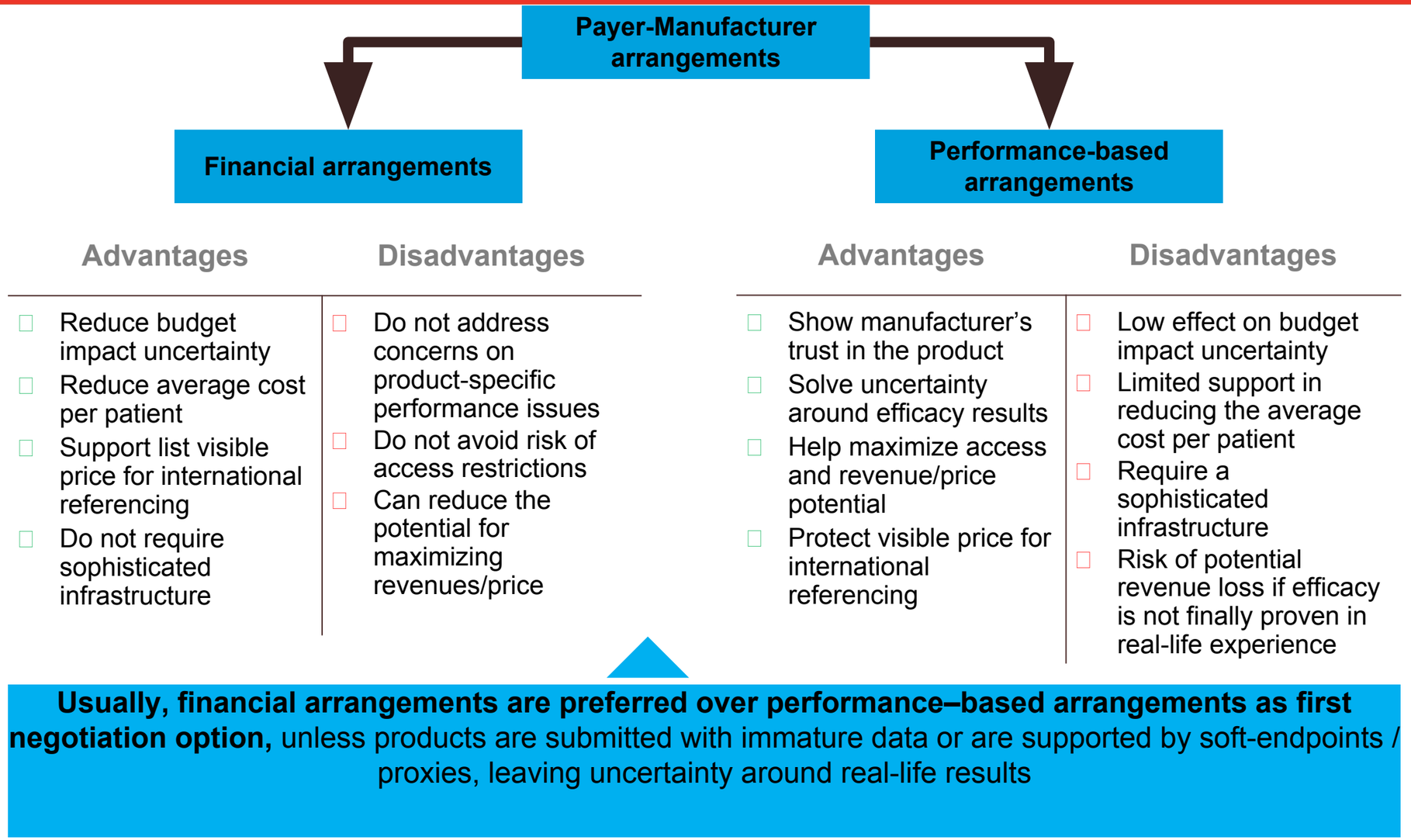
Source: (1) Eichler et al (2015) From adaptive licensing to adaptive pathways: delivering a flexible life-span approach to bring new drugs to patients, *CPT* **97**: 234-246

A range of payer programs with varying levels of complexity and uncertainty can address the value disconnect with payers



Source: Simon-Kucher & Partners – August 2016

Both financial and performance-based arrangements have their specific advantages and disadvantages



Source: Simon-Kucher & Partners – August 2016

Lilly Experience

Financial

Discounts and rebates

Price-volume

Outcomes

<u>France</u>
Agreement connecting patient adherence to reimbursement

<u>U.S.</u>
Agreement with private payer

Reimbursement based on patient success ranked on various measures

<u>U.S.</u>
Agreement with private payer

Measures lead indicators for positive patient health outcomes

Performance determines rebate levels

Long-term goal to have more value-based approaches

Barriers to success

Policy Environment (barriers to company engagement)	Unreasonable expectation of who owns the risk	Can fall heavily on manufacturer, payer, provider or patient
	“Pile-on”	When multiple payer controls are layered on top of each other: HTA + budget impact assessment + reference pricing + MEA.
	Procurement system challenges	Bids and tenders-based systems are not suitable for MEA as seeking a race to the bottom only
Data and infrastructure (barriers to all stakeholders)	Administrative challenges	Costs and practicalities of administrating a complex agreement can be high
	Poor data	Where access to data is limited, or quality is poor or if there is an inability to measure the results

Designing RSAs for success: Setting the policy framework

Voluntary

Clearly defined measures

Clearly defined timeline

Clearly defined administration and governance

Impact on access agreed

Confidential

Policy Requirements

Data must be sound and well managed

Accessibility

Data Management

Site Management

Reliable and credible

Origin

Validity

Generalizable and representative

Quality

Timely

Utility to specific objectives

Sufficiency (complete, sample size)

Relevance

Appropriate (Fit for Purpose)

Conclusion

- Bridge clinical and financial uncertainty
- Improve quality of care and patient access—for the right patients
- Provide real-world learnings
- Trending toward outcomes-based agreements
- The right policy framework and sound data generation and management can facilitate successful agreements

Scenario Exercise

Challenge:

A company presents for HTA approval an oncology product (riccumab) that has a one month survival rate. The cancer type has typically poor survival (e.g., average 1 month from diagnosis). This introduces the concept of relative benefit (i.e., +one month is meaningful if a person has only one month to live, not so much if the person has 48 months).

The product also has a poorly defined tail (i.e., while the average is one month, a few will survive many months and maybe even a year). The point here is also 1) to show that decisions are not simple, 2) to show there are limitations of an average value, and 3) to help justify why a payer might consider one month as worth considering for reimbursement.

The HTA believes overall that this product falls short of the QALY and requests a risk sharing agreement.

How would the group design it? What would be their considerations for the RSA?