Agenda

- Managed Entry Agreements: What?
- Why Relevant For Medical Devices?
- Major Challenges
- A Way Forward

Managed Entry Agreements: What?

"arrangements between a manufacturer and payer/provider that enables coverage or reimbursement of a health technology subject to specific conditions. These arrangements can use a variety of mechanisms to address uncertainty about the performance of technologies or to manage the adoption of technologies in order to maximize their effective use or limit their budget impact." (*Klemp et al, IJTAHC 2011)*

There is no universal consensus on the labelling and terminology and several taxonomies of MEAs have been proposed in the literature. There is general agreement on two clusters:

- Outcome based agreements (Performance based schemes-PBS)
- Non-outcome based agreements (Finance based schemes)

PBS: why relevant for medical devices?

- As of today, premarket evidence requirements for medical devices are less demanding
- In addition, collecting robust clinical evidence (e.g RCTs) may be unethical or unfeasible
- Thus, evidence base for estimating clinical and economic impact of medical devices is often less extensive and lower in quantity/quality
- Consequently, access to new technologies may be delayed because of the absence of scientifically sound evidence needed to respond to the expectations of policy makers deciding on reimbursement
- The distinctive characteristics of medical devices such (i.e. rapid incremental innovation, learning effects and upfront irrecoverable costs) all present additional challenge for the timing of reimbursement decisions

PBS: why relevant for medical devices?

Perceived Benefits of PBS

1. Strengthen evidence bases on the benefits and costs of new medical devices
2. Enable payers to participate in the research process.
3. Allow hospitals and clinicians to monitor more closely procedures being performed and manage costs until benefit is substantiated.
4. Encourage industry to generate the data needed to support the value claims of their innovations.
5. Allow earlier access for patients to potentially valuable medical devices than they might otherwise be granted.

PBS: why relevant for medical devices?

- A methodological framework for optimising the use of these schemes for medical devices was developed as part of the FP7 MedtecHTA Project (*Rothery et al., Characterising Uncertainty in the Assessment of Medical Devices and Determining Future Research Needs, Health Economics 2017*).

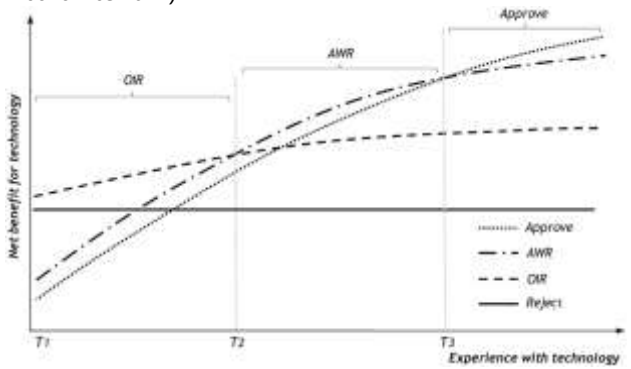

Figure 2: An illustration of coverage decisions at different points on the learning curve

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Challenges

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The Challenge of Conditional Reimbursement: Stopping Reimbursement Can Be More Difficult Than Not Starting in the First Place!

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Challenges

Objectives: To investigate how policymakers and the general public in the Netherlands value removing a previously reimbursed treatment from the basic benefits package relative to not including a new treatment.

Table 5 – Changes in predicted probability of acceptance and the CV value if the intervention already exists (compared with a new intervention).

Attribute	Average scenario	Least- preferred scenario (GP)	Most- preferred scenario (GP)
Age of patients	40	90	15
Quality of life before treatment	30	5	55
Health gain from treatment	10	5	20
Include new treatment	New -> existing	New -> existing	New -> existing
ICER	50.000	130.000	10.000
Budget impact	30 million	80 million	5 million
Probability that the cost per QALY will double	15%	25%	10%
Differences between an existing treatment compared with a new treatment within each scenario			
Change in predicted probability (GP)	+1.1%	+0.86%	+1.3%
Change in predicted probability (policymakers)	+2.8%	+1.7%	+4.2%
CV GP ICER (€)	7.360	4.146	7.414
CV policymakers (€)	7.959	60	7.971

CV, compensating variation; GP, general public; ICER, incremental cost-effectiveness ratio; QALY, quality-adjusted life-year.

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A way forward

1. Establishing a clear framework for applying PBS (e.g. deciding when they are appropriate, for what medical devices)
2. Identifying and applying appropriate research methods (e.g. RCTs, observational studies)
3. Involving all the relevant parties (e.g. manufacturers, health providers, professional groups)
4. Funding and conducting the research
5. Determining appropriate coverage arrangements based on the research findings and implementing them!

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THANK YOU

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