Markus Siebert,
Chair of the MedTech Europe Evidence & Payers WG;
Senior Director Health Economics & Reimbursement, OUS - Abbott

Some Thoughts about Funding MedTech Innovation in Europe

A MedTech Europe event

The MedTech Forum

bringing HealthTech stakeholders together

Innovation Funding Schemes in Europe

Med Tech Reimbursement Consulting

Innovative payment schemes for medical devices and in-vitro diagnostic tests in Europe

Presentation of the results of the analysis

Prepared for

MedTech Europe
from diagnosis to cure

2018 © The MedTech Forum. All rights reserved - Reproduction in whole or in part is prohibited.

High-level summary

- Out of 13 studied countries, 7 countries (54%) had innovative payment schemes in place
- On average, there 2 innovative payment schemes per country. The largest number was available in France (n=4) and England (n=3); Austria, Belgium and Switzerland had one program in place
- In total, 14 schemes were identified
- Most of the schemes (n=11, 79%) are focused on coverage with evidence development
- Three schemes (21%) are innovative funding programs with no requirements to generate evidence during coverage period
- All, but one program are focused primarily on medical technologies. One program (RIHN) is focused exclusively on in-vitro diagnostic tests

List of identified schemes

Austria
- Provisional procedure codes for new diagnostic or therapeutic methods (NUB)

Belgium
- Restricted Clinical Application for invasive medical devices and implants (Application Clinique Limité)

England
- Innovation Technology Payment (ITP)
- Innovation and Technology Tariff
- Commissioning through Evaluation

France
- Hospital Program of Clinical Research (PHRC)
- Health Economic Research Program (PRME)
- Innovation Package (forfait innovation)
- List of biological and anatomocytopathology innovative acts outside the nomenclature (RIHN)

Germany
- New diagnostic or therapeutic methods (Neue Untersuchungs- und Behandlungsmethoden, NUB)
- Government-co-sponsored studies according to the §137e of the German Social Coode Book V

Netherlands
- Conditional funding of medical technologies within Basic Health Insurance (Voorwaardelijke toelating tot het basispakket)
- Small scale experiments for introduction of innovations (Innovatie voor kleinschalige experimenten)

Switzerland
- Provisional reimbursement of medical procedures (Leistungen in Evaluation)

Snapshot of schemes

THE NETHERLANDS: CONDITIONAL FUNDING OF MEDICAL PROCEDURES

- Innovation needs to meet criteria of conformity with "science and practice"
- Initiated by Dutch Healthcare Institute
- Co-funding between manufacturer and gvt
- 19 medtech innovations selected since 2014

FRANCE: INNOVATION FUNDING

- Early support for breakthrough innovation
- Manufacturer can apply
- Fast review process (105 days)
- Co-funding
- 3 technologies since 2015

GERMANY: INNOVATION FUNDING FOR NEW DIAGNOSTIC OR THERAPEUTIC METHODS (NUB)

- Innovative technologies, whose costs are not covered (fully) by DRGs
- Only hospitals apply
- Two-tier process: INEK clearance, then price negotiations between hosp and payer
- About 9% of all applications are "cleared" for funding negotiations since 2012 (337 out of 3866)
- Out of these, 34 NUB funding agreements were made

ENGLAND: COMMISSIONING THROUGH EVALUATION (CTE)

- Good, but insufficient evidence to justify routine commissioning
- No application process, but activated by NHS England
- Fully funded by NHS England
- 7 technologies since 2014.

AUSTRIA: PROVISIONAL CODES FOR NEW DIAGNOSTIC OR THERAPEUTIC METHODS

- Provisional code for rare, innovative procedures with insufficient clinical data
- Insufficient reimbursement in the meantime
- No clinical study activated
- Hospital apply
- 50 provisional codes since 2012

Assessment from industry perspective

- **Poor Predictability**: Out of 14 schemes 10 were evaluated as having 'limited value in the planning of market access for innovation' (no manufacturer application; no involvement in study design; no possibility to initiate any other market access activities in the meantime, lack of transparency)
- Innovation and Technology Tariff (England) was evaluated as **highly relevant** (e.g. simple application process) but clinical areas are clearly defined and only **technology with proven value are allowed**
- Innovation Funding (France) was evaluated as **highly relevant** (quick process, solid option from companies good but not enough evidence to establish the procedure) but only **very limited amount of technologies** was selected (2016=1, 2017=2)
- RIHN (France) **only innovation funding** option for **IVD tests** in Europe.
- Government co-funded clinical studies in Germany **real opportunity for outpatient sector** as it is the only way for manufacturer to introduce new procedure code into the outpatient benefit catalog

Conclusions so far

Background

1. Healthcare systems need to encourage the introduction and development of innovative technologies:

2. The **European Commission** considers innovation as one of the **major instruments** for **improving patient outcomes** and guaranteeing value for **money in healthcare**.

3. There is **empirical evidence** that political support and availability of **dedicated funding** and resources may increase the likelihood of implementing innovations in healthcare.*

Current Limitations

- Dedicated funding schemes to reward innovation have only been implemented **in a few countries**, often in the form of coverage with evidence development programs.
- These schemes are typically inconsistent, non-transparent, **unpredictable** and limited in scope and time.
- There is also often no link to permanent F&R decisions causing **uncertainty** for payers, healthcare providers and industry alike.

What We Recommend

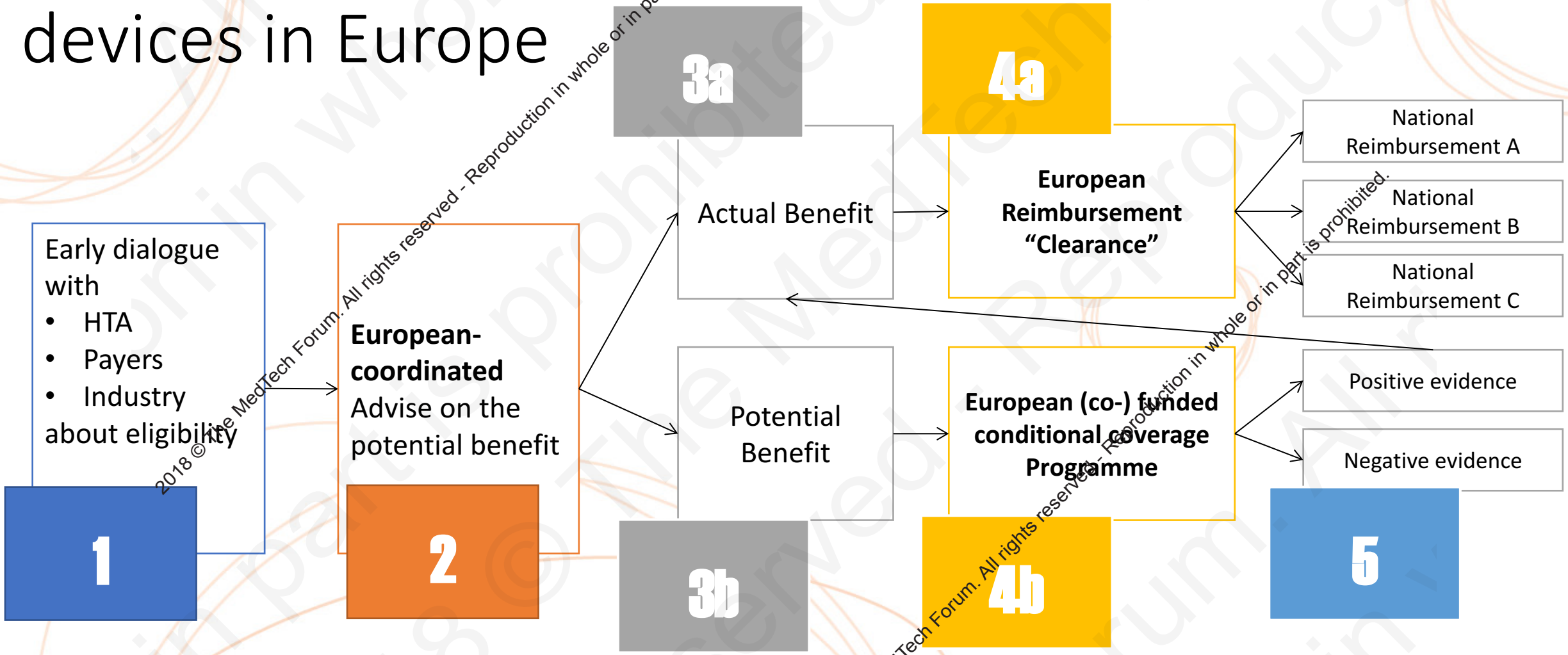
- **Specific budgets** need to be allocated to support and reward value-based innovation as a bridge to a permanent F&R decision.
- **Processes** need to be transparent and **predictable**, with manufacturers being a respected, **trusted partner**

*Mylotte et al; Journal of the American College of Cardiology, 2013

My personal proposal

2018 © The MedTech Forum. All rights reserved - Reproduction in whole or in part is prohibited.

Market access proposal for Innovative medical devices in Europe



Advantages

- Provide opportunity for Early Dialogue and Guidance for manufacturers
- Establish a coherent and predictable process on innovation funding
- Use the power of a European-level assessment of the (potential) benefit and avoid national duplication
- Speed up national decision-making processes through a European "reimbursement clearance"
- Improve capacity and speed through (co-)funding from EU research funds
- Show clear commitment from Europe to MedTech Innovation

Key Principles of Payer Engagement

- Thinking and communicating across silos and beyond hierarchies of healthcare systems
- Articulating key messages to payers that align all stakeholders around outcomes, costs, and the differing perspectives of ‘value’.
- Ensure there is an aligned message from industry towards payers
- Ensure that medical devices are kept as one of the most innovative sectors in Europe.
- Foster a community of trust between payers and the MedTech industry.

2018 © The MedTech Forum. All rights reserved - Reproduction in whole or in part is prohibited.
2018 © The MedTech Forum. All rights reserved - Reproduction in whole or in part is prohibited.