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

Presentation of the results of the analysis
High-level summary

- Out of 13 studied countries, 7 countries (54%) had innovative payment schemes in place
- On average, there were 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 Limitée)

- 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 anatomocytology 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 Code 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)
**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

**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
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*.

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*Mylotte et al; Journal of the American College of Cardiology, 2013*
My personal proposal
Market access proposal for Innovative medical devices in Europe

1. Early dialogue with
   - HTA
   - Payers
   - Industry about eligibility

2. European-coordinated
   Advise on the potential benefit

3a. Potential Benefit

4a. Actual Benefit
   - European Reimbursement “Clearance”

4b. European (co-) funded conditional coverage Programme

3b. European-coordinated
   Advise on the potential benefit

5. National Reimbursement A
   - Positive evidence

5. National Reimbursement B
   - Negative evidence

5. National Reimbursement C
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.