BACKGROUND

- While uniform rules apply for market entry of medical devices in the EU, coverage decisions by statutory health insurance companies fall within national competence according to specific procedures and criteria.
- Due to the inherent characteristics of medical devices in terms of complexity, learning curve, life-cycle and regulation, assessing at the earliest development stages, the benefit of an innovative technology for patient care is difficult.

OBJECTIVES

Objectives of this analysis are to define what are the key concepts for assessment of innovative devices at early development stages, to analyze which conditional reimbursement schemes exist in both countries and how these tools are implemented.

METHODS

Methodology for evaluating innovative medical devices by the Institute for Quality and Economic Efficiency (IQWiG) and the Federal Joint Committee (G-BA) in Germany and the Medical Devices Evaluation Committee (CNEDiMTS) of the High Authority for Health (HAS) in France.

LEGAL FRAMEWORK

- **Testing regulation (§ 137h SGB V)** allowing the G-BA to finance and initiate clinical studies to generate evidence
- **Initiated by manufacturer or following benefit assessment (§§ 135, 137d and 137h SGB V)**
- **Promising technologies**
  - less complicated or costly, less invasive
  - with fewer side effects to facilitate better treatment
- **Improvement of patient relevant endpoints**
  - i.e. prognosis, symptoms, quality of life compared to standard treatments
  - Feasibility of clinical study
- **Feasibility of clinical study**
- **Not specifically defined**
  - Only innovative technologies with a positive cost-benefit ratio are eligible

INNOVATION

- **Forfait innovation** (Art. 165-1-1 Social Security Code) consisting of fast-track assessment and temporary funding of promising and innovative medical technologies

BENEFIT/POTENTIAL

- **Feasibility and relevance of clinical/medico-economic study to confirm benefit is required**

ECONOMIC EFFICIENCY

- **Only innovative technologies with a positive cost-benefit ratio are eligible**

RESULTS

- In both countries, temporary reimbursement conditionned by the conduct of a study
- Focus on specific device in France with sole responsibility of manufacturers while in Germany focus is set on the treatment therapy
- Risks in Germany that a negative potential assessment leads to reimbursement exclusion for this indication in Germany
- In France, standard medical device assessment later possible for reimbursement purposes

CONCLUSION

- In Germany a testing regulation and early dialogue framework have been recently developed which are very similar to the ones existing for pharmaceuticals. It remains to be seen in practice how it could be applied for medical devices (i.e. RCT…). In France, fast-track for innovative devices is existing for a longer period and has led to positive assessments by HAS. In practice, few studies have been conducted so far.
- Establishing an innovation pathway at European level based on patient registries to collect uniform data would make valuable contributions to the evaluation, transparency and monitoring of such disruptive innovation at early stages.

REFERENCES

- § 137h Sozialgesetzbuch V (SGB V)
- Art. 165-1-1 du Code de la Sécurité Sociale