ASSESSMENT OF INNOVATIVE MEDICAL DEVICES: PROVING THE BENEFIT FOR THE PATIENT

BEST PRACTICES FROM GERMANY AND FRANCE

Plaud, Marie-Geneviève; Kühl, Malte; Ecker, Thomas

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 and key concepts

LEGAL FRAMEWORK	• ***Testing regulation*** *(§ 137e SGB V) allowing the G-BA to finance and initiate clinical studies to generate evidence* • *Initiated by manufacturer or following benefit assessment (§§ 135, 137c and 137h SGB V)*	• *„**Forfait innovation**“ (Art. 165-1-1 Social Security Code) consisting of fast-track assessment and temporary funding of promising and innovative medical technologies* • *Initiated by manufacturer*
INNOVATION	• Promising technologies - **less complicated or costly,** - **less invasive** - **with fewer side effects** to facilitate better treatment	• Cumulative criteria in terms of: - **novelty** and **early dissemination**, - **patients safety** - **clinical benefit** and/or **healthcare expenses**
BENEFIT/ POTENTIAL	• Improvement of **patient relevant endpoints**, i.e. prognosis, symptoms, quality of life compared to standard treatments • **Feasibility of clinical study**	• Feasibility and relevance of **clinical /medico-economic study** to confirm benefit is required
ECONOMIC EFFICIENCY	• Not specifically defined	• Only innovative technologies with a **positive cost-benefit ratio** are eligible

Case study : High-intensity focused ultrasound technology

✓ **HIFU for the treatment of uterus fibroids (2016)** • *Potential acknowledged* following § 137h SGB V • Decision based on outcomes on: - *QoL and symptoms-related from a non-RCT study* - *non patient-relevant endpoints from a RCT study* > G-BA decision: Testing with a **RCT with patient-relevant** endpoints required to confirm potential	✓ **HIFU for the treatment of prostate carcinoma (2010)** • *Positive assessment* of HAS for temporary funding • Cumulative criteria met and positive cost-benefit ratio expected > CNEDiMTS decision: Clinical study not feasible, however testing with a **comparative study** required > Reimbursement decision in 2014
✓ **HIFU for the treatment of endometriosis (2017)** • *No potential acknowledged following* § 137h SGB V • *No RCT study submitted*, only case series and non-randomized clinical studies > G-BA decision: Technology should be **excluded from reimbursement**	✓ **HIFU for the treatment of benign tumours of the breast and thyroid (2016)** • *Positive assessment* of HAS for temporary funding • *Cumulative criteria met* and *positive cost-benefit ratio* expected > CNEDiMTS decision: Testing with a **non-inferiority study vs. surgery required** > Reimbursement decision in 2017

RESULTS

> In both countries, temporary reimbursement conditionned by the **conduct of a study**

> Focus on **specific device in France** with sole responsability 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**

RESULTS

> In Germany, G-BA expectations concerning evidence for innovative devices at early stages of development are high

- Similitude with the evidence level required for the **early benefit assessment of medicinal products** under AMNOG
- Risks of **exclusion of innovative devices from the German market in the long-term** with **underlying consequences** for patients

> In France, a dozen of positive decisions have been taken by the HAS pursuant to the “forfait innovation”. However, in practice **the procedure is very intransparent** and only **a few studies** have been conducted so far.

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

- § 137e Sozialgesetzbuch V (SGB V)
- Art. 165-1-1 du Code de la Sécurité Sociale
- Bewertungen gemäß § 137h SGB V, Gemeinsamer Bundesausschuss, https://www.g-ba.de/informationen/verfahren-137h/ (last accessed: 10.2017)
- Institut für die Qualität und Wirtschaftlichkeit im Gesundheitswesen, https://www.iqwig.de/ (last accessed: 10.2017)
- Haute Autorité de Santé, www.has.fr (last accessed : 10.2017)

Ecker + Ecker GmbH . Warburgstr. 50 . 20354 Hamburg . Germany
Phone: +49 (40) 41 330 81-0 . E-Mail: info@ecker-ecker.de . Internet: www.ecker-ecker.de

Für die elektronische Version der Poster der ISPOR 2017 scannen Sie bitte den QR-Code.