

# Medical Devices Assessment in Europe: Where Do We Stand? Inspired by Perspectives from England and Germany

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## KEY POINTS . . .

The assessment of medical devices in a health technology assessment framework may offer some challenges with respect to available data.

Different countries will deal in different ways with the uncertainty attached to weaker data packages.

Some assessment processes can be complex and have to take into account local reimbursement paths.



## General Background on HTA and Medical Devices in Europe

In Europe, health technology assessment (HTA) typically focuses on considering evidence for an intervention in the context of medical and clinical efficacy, sometimes combined or followed by an assessment of its economic impact on health care resources at regional and local levels.

Over the last 20 years, the focal point of payers and regulators for HTA has been drug treatments. A wealth of experience has been gained by individual agencies in Europe (collectively leading to EUnetHTA being created in 2005), that aims to enhance collaboration between countries to ultimately improve HTA decision making.

Ever since medical devices came into play, the question has been “Is there a difference between drugs and medical devices for the assessment?” It has become increasingly important to structure the approach to medical devices from a European regulatory perspective, but also from technical and economic HTA standpoints. It is important to highlight that to date, very few countries have a structured approach to assessing medical devices.

Medical devices are similar to drugs in the sense that they bring value to patients’ health in supporting improved diagnosis and treatments of medical conditions. However, devices differ from drugs in their inherent multiple applications, as well as the fact that devices are often used for diagnosis purposes, which is earlier in the patient care pathway than we are used to with drugs. This does not make it less critical for enhancing health outcomes, it only adds a layer of complexity for the clinical and economic evaluation.

Generating evidence as stringent as for what’s needed in the development for drugs is frequently a hurdle for medical devices. The difficulties experienced in conducting robust randomized controlled trials (RCTs) are characterized by the impact on efficacy of ongoing product modifications on the one hand and much shorter product and

innovation cycles on the other hand. Moreover, blinding for clinical studies remains challenging as “sham” procedures are often not ethical in specific situations where double-blinding is not possible. Another important consideration is the fact that medical devices often are developed and marketed by smaller manufacturers, thus representing a substantial limitation to undertaking research and generating evidence on a larger scale comparable to drugs.

One final argument that is often discussed is the fact that learning curves play a very prominent role for the effectiveness of medical devices in the daily setting. Unlike drug products, where a biological process is started when a compound enters the system leading to a response (or not) based on biological factors that are beyond the skill of the treating clinician, the skill set may be critical in the application of a new medical device. Learning curves logically are lower at market entrance as a skillful user might yield much better results after market penetration and gained experience (which can negatively bias results for efficacy).

Nevertheless, despite many challenges, the medical device industry should also have an interest in producing as much relevant evidence on clinical efficacy, safety, and impact on validated clinical outcomes as possible.

In the end, manufacturers need to be prepared to translate different facets of demonstrated added value to a matrix of quite diverse stakeholders (regional/local payers, regulators, health care professionals, etc.). In the current climate of austerity in Europe, aligning the economic value to the clinical arguments is critical for health care providers. Budget impact analysis (BIA) is gaining paramount importance in price negotiations, but there is also an opportunity to make it clear that services around a product have a potential to enhance the outcomes for the patient.

In the ISPOR Panel, it was discussed how these challenges may be overcome by

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regulatory agencies trying to focus the discussions by using examples from current regulations in two major economies in Europe, the UK, and Germany.

## The English Approach to Medical Devices

England and more precisely NICE (National Institute for Health and Care Excellence) is one of the few HTA bodies in Europe that has adopted a procedure to assess medical technologies separated from drugs.

### *The assessment process*

In order to have a medical device assessed, the manufacturer has to notify NICE through a standardized form. The information requested is very similar to what's required in a drug HTA and focuses on the population, the indication, comparators, costs (one-off and on-going), safety concerns, if any, and the expected benefits translated in health outcomes expected. Any claims have to be supported by evidence, as it is expected to be in any HTA process. The only deviation to the "classic" approach is the requirement to include benefits to the health system (e.g., procedures avoided, inpatients days avoided etc.), as well as the ability for the manufacturer to nominate experts that can be consulted by NICE if necessary.

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Upon receipt of the notification, NICE assesses the technology against the eligibility criteria, which can be found below:

- Requirement to have a CE mark (or equivalent regulatory approval) or it has to be expected within one year
- The topic being within NICE's remit and is not currently being evaluated
- The new or innovative nature of the technology, with claimed benefits for patients or health care systems

Supposing that the technology meets the criteria above, NICE will compile a briefing on the technology. It will then be transmitted to the MTAC (Medical

Technology Advisory Committee), which operates as a standing advisory committee of the Board of NICE. It usually includes 25 independent specialists with a broad range of medical technology and evaluation expertise that meets monthly. The decision will then be made on whether or not the technology should be assessed according to the briefing note. To increase the likelihood to be evaluated, the manufacturer should include information on substantial benefits to patients and/or the NHS compared with current practice, stating clearly demonstrated advantages offered over current practice based on robust evidence and information on costs. Evidently, it may be beneficial if there was a NICE guidance developed or in development on the technology under consideration.

For the selected technologies, the committee must direct to the most appropriate NICE process for evaluation: Technology Appraisal, Diagnostics Appraisal Committee, Medical Technologies Evaluation, Clinical Guidelines, Interventional Procedures, or non-NICE programs (e.g., NIHR HTA Research Programme).

UK policy makers in general believe that an HTA approach is an effective tool to assist in health care decision making, even

Despite the pragmatism, NICE has often concluded in individual assessments that there is simply not enough evidence to support a worthwhile evaluation. Although there is a place for classical experiments, randomizing patients, or inferring from routine or robust data will have to be used as a reference.

## The German Approach to Medical Devices

### *The current assessment process in Germany*

Germany is another country to just have enacted a procedure to assessing medical procedures in the future, which may include medical devices; however, medical devices are very rarely assessed on their own until very recently. The general principles of evaluation for medical procedures remains the same as for drugs, with the G-BA (Federal Joint Committee) taking the decision after commissioning the IQWiG (Institute for Quality and Efficiency in Health Care) with the detailed assessment of a medical intervention.

For reimbursement, there are different regulations for in-hospital products and ambulatory care products according to the Social Code of Law V (SGB V). In fact, technologies may be used in the hospital setting unless the G-BA decides otherwise in a formal process, and they may not be used in ambulatory care unless G-BA decides in their favor on beforehand. One of the reasons for this difference comes from a belief that clinicians in a hospital have a wider experience with new medical technologies and hence, the risks for application are less imminent for patients.

For hospital care, reimbursement is primarily based on a standard 2,000+ DRGs (German Diagnoses-related Groups) system, organized by the Institute for Hospital Remuneration (InEK), which updates the DRG codes and relative weighing of cases on a yearly basis to reflect changes in medical innovation and changing cost structures. However, it is important to note that the InEK does not assess the effectiveness of medical interventions.

Two different situations can potentially occur. If the new medical device is part of an existing procedure, it may require an add-on remuneration or new DRG. However, if the new medical device is a

key element of a new procedure, it always requires the creation of a new DRG.

The reimbursement path is not the same in ambulatory care, as it depends on the type of medical device. In many cases, a prior decision of the G-BA is needed and a joint evaluation of the new technology is undertaken on both the hospital and ambulatory care level. Subject to the clinical and/or economic importance of the device, IQWiG may be asked to provide a thorough assessment of clinical effectiveness. However, if a new medical device can be included in an existing group of technologies where reimbursement was granted in the past, that technology will have to accept the existing historical lump sum remuneration for that class of medical devices or technologies.

### **The future of medical device assessment in Germany**

At the moment, there is no structured process specific to medical devices in Germany; G-BA and IQWiG do not evaluate classes of medical devices or individual devices; they only evaluate medical procedures, which may include the use of medical devices.

Recent regulatory changes were introduced in December 2015 for the assessment of high risk class IIb or III medical devices for which hospitals apply for extra payment on top of the DRG payment scheme. Hospitals may apply once a year for extra

funding in the subsequent year for drugs, devices, and procedures under the so-called NUB (Neue Untersuchungs- und Behandlungsmethoden) scheme. In the past, all applications were assessed by the InEK without stringent focus on efficacy but more on information, (i.e., if current cost structures are adequately addressing the cost of the innovation, whether the impact of the new technology and/or procedure is significant, etc.). In the future, should a single hospital apply for a NUB for a medical device that a) is invasive a completely new technology and that represents (not just a modification of an approach that is already known in clinical practice), the hospital and the manufacturer must provide clinical evidence at the time of application. The aim of the following assessment, as a minimum requirement, is whether the new technology has the potential to have a positive impact on patients. If that is the case, the hospital and the manufacturer will be asked to develop clinical evidence (i.e., conduct clinical research) that will be agreed upon with the G-BA.

In the newest version of the general methods applied by IQWiG for its assessments, there already is a specific section on non-drug interventions stating that non-randomized studies may be considered in the assessment; however, the quality standards and principles of evidence-based medicines also apply to such studies.

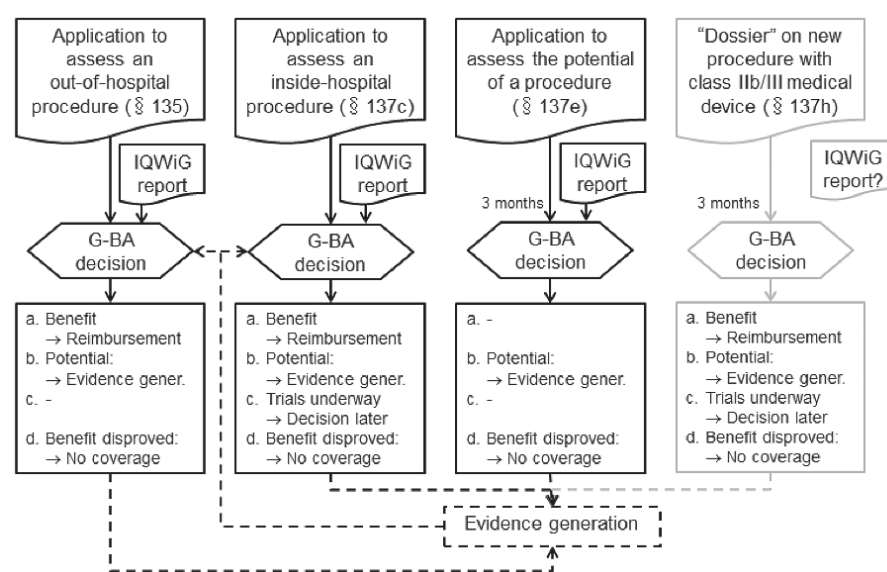
## **Conclusion**

In the future, some essential concerns will have to be addressed in order to improve the safety of patients and the uncertainty of payers and regulators about outcomes and costs of medical devices. Indeed, proof of efficacy and (added) clinical benefit is not typically necessary to receive a CE certificate for general market clearance; therefore new products may be ineffective or even put patients at risk. Adding to that, there is no strong policy in place pushing manufacturers to publish essential and medically relevant information for doctors and patients in this segment.

To address these shortcomings, there are different attempts in Europe to define a path for medical devices, whether it is a full separate process or partly embedded in the current assessment processes. Hiccups during such assessments with respect to weaker available evidence at market entrance (due to the very nature of many medical devices making clinical research—or the interpretation of results—more complicated) can be faced and overcome, as long as value to patients and health care systems is clearly defined in a transparent HTA framework. It is essential to keep in mind the fundamentals of HTA as a systematic process accepting many different layers of evidence and uncertainty in the evidence presented. The result of an individual assessment will play a paramount role in health care decision making as these assessments safeguards patients' outcomes and safety, while taking into account the economic aspects for single health care systems. ■

**Figure 1. Current and future pathways of HTA of non-drug interventions.**

(courtesy of Alric Rüther)



### *Additional information:*

*The preceding article is based on the issues panel, "Assessment of the Value of Medical Devices: Can We Simply Apply Processes Established for Drugs or Do We Need to Pursue Separate Processes for Devices?" at the ISPOR 18th Annual European Congress, 7-11 November 2015.*

View this presentation at:  
<http://www.ispor.org/Event/ReleasedPresentations/2015Milan#issuepanelpresentations>