New digital health applications (DHA) reaching the health care market and some have already proven a clear benefit for patients through RCTs. But how is it with the market access in different countries? Some countries have DHAs similar to other health care products, others have implemented a special pathway. The objective of this analysis is to examine DHA market access routes in Germany, France and the UK.

Methodological, within the included countries, respective national authority websites were screened for formal pathways, national laws and regulations by conducting targeted literature searches. Additionally, market access expert interviews were executed.

**UK: DHTs & MTEP**

In the UK, the Medical Device Regulations or the National Health Service (NHS) digital safety regulations are responsible for the assessment of safety of digital health technologies. However, to facilitate the decision-making process, in 2019 NICE developed a framework which provides a set of evidence standards that should be used to show the value of digital health technologies in the UK healthcare system.

Digital Health Technologies (DHTs) are defined in between the Evidence Standards Framework for Digital Health Technologies. They are classified by function and stratified into evidence tiers:

- **Tier 1:** DHTs with potential system benefits but no direct user benefits
- **Tier 2:** DHTs which help users to understand healthy living and illnesses but are unlikely to have other significant health benefits
- **Tier 3a:** DHTs for preventing and managing diseases. They may be used alongside treatment and will likely have measurable user benefits
- **Tier 3b:** DHTs with measurable user benefits, including tools used for treatment and diagnosis, as well as those influencing clinical management through active monitoring or calculation. It is possible DHTs in this tier will qualify as medical devices.

There are different evidence requirements depending on the tier where the technology falls into. The two main evidence classes required are effectiveness and economic impact.

The Medical Technologies Evaluation Programme (MTEP) evaluates any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, together with any accessories including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human being for the purpose of:

- Diagnosis, prevention, monitoring, treatment or alleviation of disease
- Diagnosis, monitoring, treatment, alleviation or of compensation for an injury or disability
- Investigation, replacement or modification of the anatomy or of a physiological process or function
- And which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means

MTEP aims to evaluate medical devices that are deemed to be cost-saving or cost-neutral and produce Medical Technology Guidance (MTG) to encourage their adoption. For medical technologies routed to the MTEP for MTG, the MTEP produces an adoption recommendation in a MTEP. (Figure 1). However, unlike Technology Appraisals, a positive adoption recommendation from MTEP does entail a funding mandate for NHS England.

**GERMANY: DIGA FAST TRACK**

With the Digital Healthcare Act (Digitale-Versorgung-Gesetz, DVG), decided on 19 December 2019, the “app on prescription” for patients (Sections 33a and 139e of the German Social Code Book V) was made possible in the German healthcare system through the DIGA Fast Track (Figure 2).

The process is divided into two parts. The BIARM (Bundesinstitut für Arzneimittel und Medizinprodukte - Federal Institute for Drugs and Medical Devices) is responsible for evaluating an application and the GKV-SV (Spitzenverband der Geisteskrankenhäuser - Head Association of the Statutory Health Insurances) is responsible for the price negotiations.

If there is no evidence submitted (or in the process of generating or considered as weak) the listing and reimbursement can be limited for one year with resubmission new evidence after this. DHAs are defined as applicable for the DIGA Fast Track (Section 33a of the German Social Code Book V), if the...

- Medical device is CE-marked
- Medical device of the risk class I or IIa (according to the Medical Device Regulation (MDR) or the transitional regulation Medical Device Directive (MDD)).
- Main function of the DGA is based on digital technologies.
- Medical purpose is mainly achieved by way of its digital function.
- DIGA supports the recognition, monitoring, treatment or alleviation of diseases or the recognition, treatment, alleviation or compensation of injuries or disabilities.
- DIGA is used by the patient alone or by patient and healthcare provider together.

**FRANCE: DIGITAL HEALTHCARE**

In France, digital therapeutics could be funded through the standard P&R procedure regarding medical device: the first step is the medico-technic assessment by the CNEIDMts (Commission nationale d'évaluation des dispositifs médicaux et des technologies de santé). The Medical device and health technology Evaluation Committee, has the committee is in charge of the medical device assessment (Figure 3).

Firstly, the CNEIDMts gives an opinion on the actual medical benefit called “SA”. The opinion about SA determines whether the connected medical device is reimbursed (SA sufficient) and the rate of its reimbursement by the French national health insurance (important SA: 65 % reimbursement, moderate: 30 %; low: 15 %) or not (insufficient medical benefit). The SA must take into consideration: severity of the disease, efficacy/adverse effects ratio, intended role in the therapeutic strategy and is in comparison with the other available interventions, public health benefits. To be eligible for reimbursement, the digital therapeutics have to demonstrate a sufficient efficacy/safety ratio in a robust clinical study. The HAS published guidelines to explain how to develop a digital therapeutic product in order to be approved. They are used as a reference for the French HTA requirements and which elements are needed to be favorably assessed by the CNEIDMts. If the SA is judged sufficient, the CNEIDMts also gives its opinion on the “Added Medical benefit” (AS) as well as “actual clinical benefit”. The added medical benefit measures the digital therapeutic added clinical value compared to existing interventions already reimbursed and is used to determine the price. By giving an AS I to III, the committee judges that the digital therapeutic is an innovation. With an AS IV, the new digital healthcare product brings a minor improvement compared to the current strategy. With an AS V: the committee judges that there are no improvements of the clinical value compared to other alternatives.

The second step is the negotiation of the digital therapeutic price. The company and the CEPS negotiate the price of the digital healthcare product.

For digital therapeutics which are not eligible to the standard P&R procedure in the absence of robust demonstration of their clinical efficacy/safety, other pathways are possible: “futur innovation”, telemonitoring experimentation (in five pathologies) or article 51.

**SUMMARY:**

When looking overall at the processes, they differ within the area of market access for drugs. Overall we identified four market access pathways. In France the standard market access routes for medical devices was also used to apply to DHAs. In the UK, two different pathways were identified: Medical Technologies Evaluation Programme and a new Evidence Standards Framework for DHAs. In Germany, with the DIGA Fast Track a new legislation has been implemented with the opportunity of permanent or temporary reimbursement with evidence generation.

In France, the process lasts between 4-6 months for the assessment whereas the time for price agreement is highly variable lasting up to 2 years. In Germany, the DHA registration lasts maximum of 3 months and the price negotiation is set for a maximum of 1 year. In the UK, DHAs are free priced with patient access available from launch, with the two pathways designed to evaluate the value of DHA to the NHS. A close comparison between France, UK and Germany is made regarding the price of DHA, and in the UK, DHAs are free priced with access from launch whereas in France are available after price approval.

**REFERENCES:**

- **BfArM 2020:** Digita Gezielungsanweisungen (DIGa) (https://www.bfarm.de/DE/Medprodukte/DIGa/index.html, accessed 04.11.2020)
- **BfArM 2020:** DIGA Verzeichnis (https://www.bfarm.de/de, accessed 04.11.2020)