Comparison of Market Access Routes of Digital Health Applications in France, Germany and the UK

PMD17

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INTRODUCTION:

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: Different countries handle 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, Medical Device Regulations or the National Health Service (NHS) digital clinical 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 measurable user outcomes
- 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.

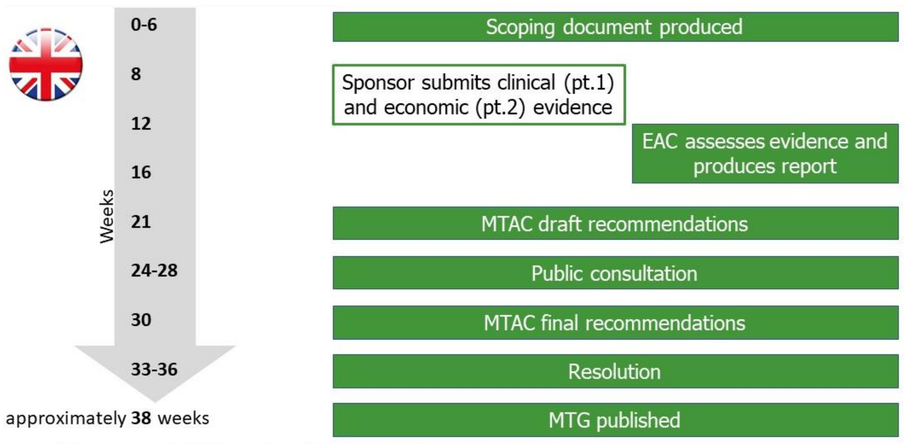
There are different evidence requirements depending on the tier where the technology falls into. The two main evidence classes required are effectiveness and economic impact.

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 of or compensation for an injury or disability
- Investigation, replacement or modification of the anatomy or of a physiological process
- Control of conception
- 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 MTG (Figure 1). However, unlike Technology Appraisals, a positive adoption recommendation from MTEP does entail a funding mandate for NHS England.

Figure 1. Medical Technologies Guidance: Market Access steps



EAC: External Assessment Centre; MTAC: Medical Technologies Advisory Committee; MTG: Medical Technologies Guidance

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).

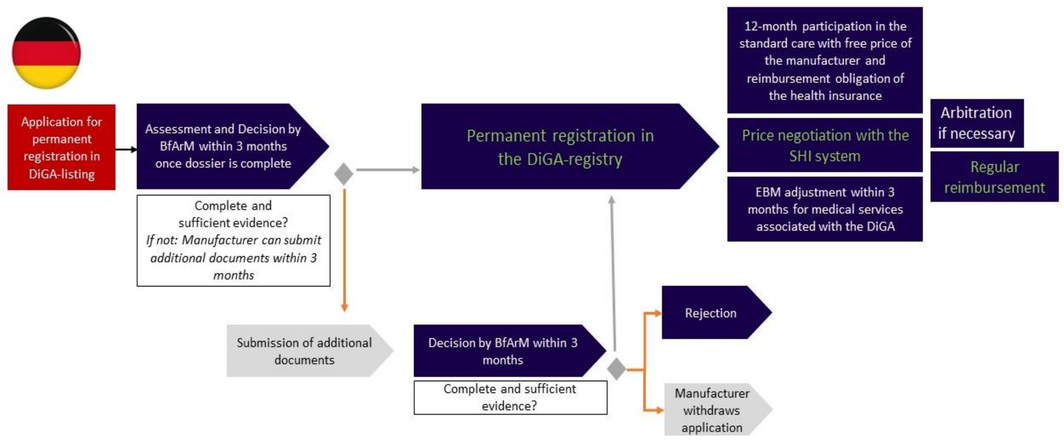
The process is divided into two parts. The **BfARM (Bundesinstitut für Arzneimittel und Medizinprdoukte** - **Federal Institute for Drugs and Medical Devices)** is responsible for Evaluation & Assessment and the **GKV-SV (Spitzenverband der Gesetzlichen Krankenkassen - Head Association of the Statutory 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 resubmitting new evidence after this.

DiGAs 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 DiGA 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.

Figure 2. DIGA Fast Track: Market Access steps



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 **CNEDIMTs (Commission national d'évaluation des dispositifs médicaux et des technologies de santé – Medical device and health technology Evaluation Committee),** the **HAS committee** is in charge of the medical device assessment (Figure 3).

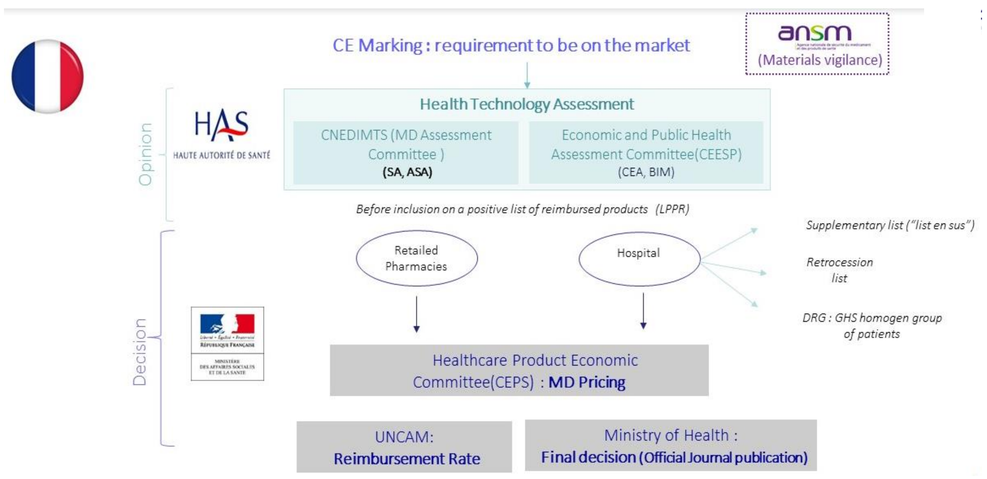
Firstly, the CNEDIMTs gives an opinion on the actual medical benefit called "SA". The opinion about SA determines whether the connected medical device is reimbursed (SA sufficient) and the rate of its reimbursement by the French national health insurance (important SA: 65 % reimbursement, moderate: 30 %; 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 in comparison with 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 which complies with the French HTA requirements and which elements are needed to be favorably assessed by the CNEDIMTs.

If the SA is judged sufficient, the CNEDIMTs also gives its opinion on the "Added Medical benefit" (ASA) also called "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 ASA I to III, the committee judges that the digital therapeutic is an innovation. With an ASA IV, the new digital healthcare product brings a minor improvement compared to the current strategy. With an ASA 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, others pathways are possible: "forfait innovation", telemonitoring experimentation (in five pathologies) or article 51.

Figure 3. Digital Healthcare: Market Access steps



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 core difference between France, UK and Germany is the availability of the DHAs. In Germany and UK DHAs are free priced with access from launch whereas in France are available after price approval.

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