Digital Health

HTA68

Where Do We Stand From a Market Access Perspective in the EU-4 and the UK?

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Objectives

- To assess the market access and pricing processes for digital health applications EU-4 (France, Germany, Italy and Spain) + UK and determine the key decision making criteria.

Methods

- National laws and regulations were assessed via targeted literature research, including official health technology/reimbursement agency websites. Additionally, expert interviews were conducted.

Targeted literature research

Expert interviews

United Kingdom

Local health authorities have freedom to fund health apps that align with their local objectives. Funding comes from local budgets.

Guidance exists but is not linked to national reimbursement:
- Evaluation by NICE (MTEP) assesses the cost-effectiveness and makes recommendations on adoption
- ESF - NICE guidance on classification of DHTs and evidence standards (recommends high clinical evidence standards)
- DTAC - NHS Criteria on safety, data protection, technical security, interoperability, usability and accessibility

Only one of two apps assessed under NICE's MTEP has been recommended so far – Sleepio app (May 2022)

- A new Early Value Assessment for Medtech which offers rapid assessments of the clinical effectiveness and value for money of new digital therapeutics has been announced. A pilot scheme began in June, assessing two apps that target depression and anxiety in children.
- Accreditation by independent organisations (QISMET, ORCHA) can be used in place of NICE/NHS criteria to inform decision-making locally.

DHT reimbursement processes are evolving and should be monitored as it is rapidly evolving. Level of evidence to support reimbursement is anticipated to be high based on current NICE evaluations

France

There is no specific pricing and reimbursement (P&R) pathway for digital health applications.

Common evaluation for medical device based on robust clinicals data demonstrating clinical effect benefit is required by HTA body

- Since 2020, MOOVECARE®[8] is the only reimbursed digital health app.
- The second one may be covered by health insurance, since DEPREXIS®[9]
- Obtained a positive opinion from the HTA (CNEDIMTs) in September 2022

For DTx : 'anticipated derogatory pathway', average 1 year prior their evaluation through the common P&R pathway , should occurred (decree would be published by end 2022)
➔ to ensure early access to innovation.

Italy

Ratifying of the agreement "National guidelines for the provision of telemedicine services" by the State Regions Conference in 2020. The agreement provides the guidelines to be adopted for the provision of telemedicine services. Aim: ensure that telemedicine services represent a concrete element of organizational innovation in the care process.

Only "Essential Levels of Care" are provided by the NHS. Some regions have included "televisitis" in the tariff for F2F visits.

Recovery and Resilience Plan:
- Around 2.5 billion Euros will be invested in digital health in the next years.
- Strengthen prevention and health services in the area modernize.
- Digitize the health system in order to ensure equal access to effective care.

Spain

There is no specific P&R process for digital health applications. However, some regional health authorities have developed assessment frameworks and certification systems for mobile applications, including Andalusia and Catalonia, respectively.

- Andalusian Agency for Healthcare Quality Health Apps Catalogue includes 39 Apps (AppSaludable Quality Seal), 81 apps in the assessment process, and a future certification program in development.
- TIC Salut Social Foundation (entity attached to the Catalonian Department of Health) has certificated 9 App.

In 2022, the Catalan Agency for Health Quality and Evaluation (AQUAS) published a report for the Spanish Network of Agencies for Assessing National Health System Technologies and Performance (RedETS), including a tool for mHealth health technology assessment. Within the scope of the RedETS, the evaluation of 2 apps is planned for 2022.

Germany

A new fast-track process was implemented in 2020.

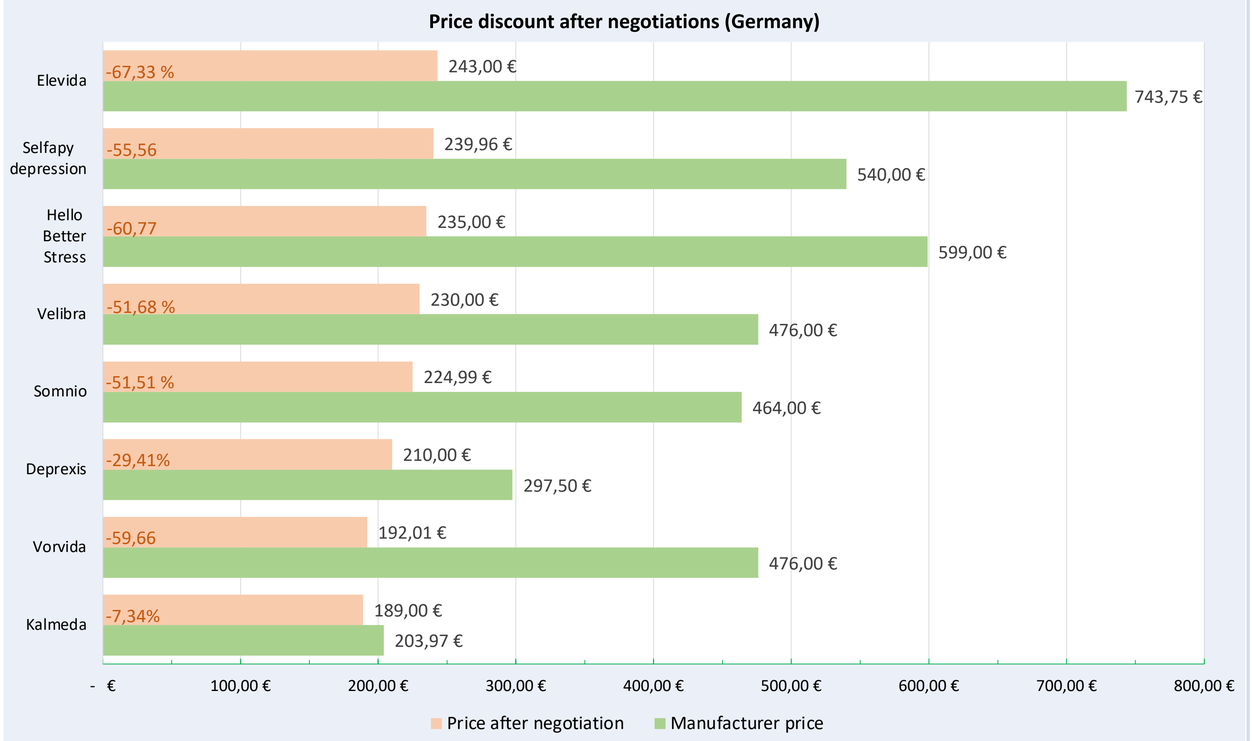
130 applications were submitted as of May 2022.

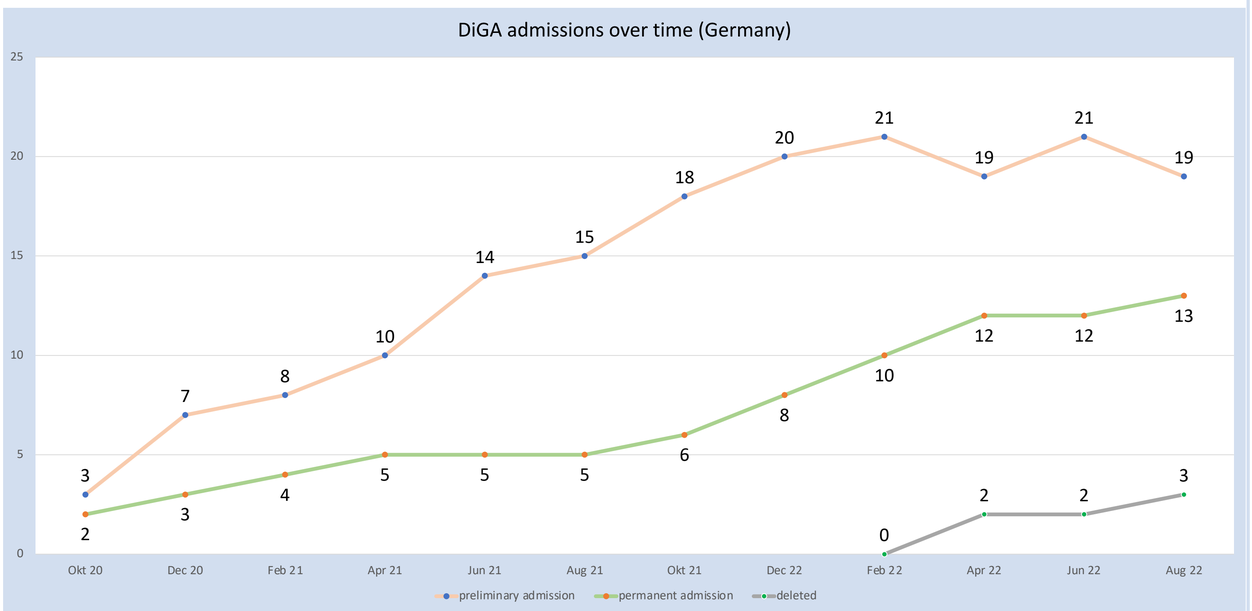
31 were accepted temporarily.

The first 5 DiGAs went through price negotiations with agreed discounts of up to 67%

The fast Track procedure:

- Manufacturer submits an application,
- BfArM advises and examines,
- ✓ Requirements fulfilled: Preliminary admission.
- ✓ Requirements + Positive care effects fulfilled: Admission into the DiGA-directory and price negotiations. If necessary: arbitration.



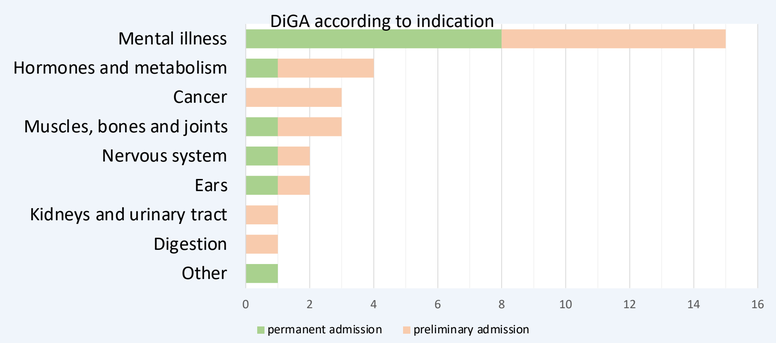


References

[1] MArS Market Access & Pricing Strategy GmbH, Weil am Rhein, Germany and Medvance Germany;
[2] University of Applied Sciences, Loerrach, Germany;
[3] Weingarten-Ravensburg University of Applied Sciences, Weingarten, Germany;
[4] Intexo Srl, Milan, Italy and Medvance Italy;
[5] Nextep, Paris, France and Medvance France
[6] Outcomes 10, Castellón de la Plana, Spain[7] Remap, Manchester, UK and Medvance UK
[8] HAS evaluation april 2019
[9] HAS evaluation september 2022

Conclusion

Although there are similarities between the EU4 + UK for the market access of digital health applications, processes vary between countries. As it can be seen in Germany, an improved pathway through a fast-track path can lead to faster and broader market access to patients.



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