WRITTEN BY

KLAUDIA POPÉLYOVÁ
Life Sciences Associate
Ments s.r.o.

LUKÁŠ MICHÁLIK
Life Sciences Partner
Ments s.r.o.

ments attorneys

THE RISE OF DIGITAL THERAPEUTICS

Digital therapeutics (DTx), software-based interventions for health disorders or diseases, are gaining traction. The rise in digital tools usage has increased the demand for digital therapeutics. They can be standalone or used with other treatments to improve patient care.

Digital therapeutics are evidence-based therapeutic interventions driven by software programs. Their aim is to prevent, manage, alleviate, or treat medical disorders or diseases. Digital Therapeutics can be used independently or in conjunction with medicinal products, devices, or other therapies to optimize patient care and health outcomes. According to the Regulation (EU) 2017/45 of the European Parliament and of the Council of 5 April 2017 on medicinal devices (MDR), digital therapeutics are classified as Medical Device Software. There are three main types of digital therapeutics:

- **Standalone DTx:** These function independently of any other medical product and are used to deliver therapeutic interventions on their own.
- **Companion DTx (disease-specific):** These are used alongside medicinal products, devices, or other therapies to improve patient care and health outcomes. A single companion DTx can potentially accompany different therapies.
- **Combination digital therapeutics (product-specific):** These consist of software and one or more other components (medicinal product – software, medicinal device – software, medicinal product – medicinal device – software) that are intended to be used together.

DTx cover a wide range of therapeutic areas and rely on various digital health tools, including apps, web-based interventions, and virtual reality. They can interact with hardware components like wearable measurement devices. It's crucial to differentiate between digital health tools and DTx. While digital health tools include a broader range of health-related technologies and platforms, DTx specifically focus on delivering evidence-based therapeutic interventions.

The beneficiaries of DTx include patients, clinicians, and the overall healthcare system. DTx can empower patients by enhancing their experience and outcomes, coordinating their care, and fostering collaboration with healthcare providers. For instance, some DTx are designed to treat depression and low moods through Cognitive Behavioral Therapy[1].

For clinicians, DTx offer alternative or superior therapeutic options, enhancing overall treatment monitoring and patient care information. They often facilitate data sharing between patients and healthcare professionals. For instance, certain epilepsy treatment tools collect data that can be directly shared with clinicians.

DTx could serve healthcare systems by addressing unmet needs or underrepresented areas of healthcare, leveraging their unique features and benefits to patients. For example, DTx could be introduced in cases with limited or inadequate treatment options, thereby addressing unmet needs and easing the burden on the healthcare system. A digital therapy used for lung cancer patients reduced the use of imaging procedures by 49% per patient per year compared to standard care and was found to be cost-effective in reducing follow-up costs compared to conventional monitoring[2].

Accessing the market for digital therapeutics in the European Union contains several barriers. A primary obstacle is the lack of harmonized regulatory requirements across EU member states, due to differing interpretations. Currently, only a few EU member states, have adopted legislation regarding Digital Therapeutics. However, Germany, Belgium, and the United Kingdom serve as notable exceptions.

Germany was the first country to adopt a Digital Healthcare Act, also introducing a fast track for qualifying apps, which, once included in the centralized system, are eligible for reimbursement.

Belgium established a unique access path for digital therapeutics via the mHealthBelgium platform, only reimbursing apps that have earned a CE mark as a medicinal device and evaluates them using the "validation pyramid". Only DTx which fulfill both conditions are eligible for reimbursement.

While the United Kingdom has made progress in establishing a value assessment framework for DTx, its access pathways are not as developed as those in Germany or Belgium. The National Institute for Health and Care Excellence (NICE) classifies DTx based on their functions and stratifies them into evidence tiers according to potential user risk. However, there is no funding mandate for digital health technologies recommended by NICE, except for digital cognitive behavior therapies which have conditional recommendations as part of an Early Value Assessment pilot.

Another significant barrier lies in the lack of processes for DTx Value Assessment, particularly regarding the evidence required for positive value assessment. Concerns arise that payers may expect all DTx to be backed by evidence from Randomized Controlled Trials (RCTs), which aren't always the most suitable approach for generating DTx evidence. This further complicates the issue that evidence requirements aren't standardized across countries, causing challenges for companies in developing their clinical plans. This may slightly change once the EU HTA starts with health technology assessment as some of the medicinal devices will be subject to Joint Clinical Assessment.

EU member states lack standardized reimbursement pathways for DTx, resulting in prolonged decision times, despite the clinical benefits which shall warrant reimbursement by health systems.

Insufficient funding for DTx, coupled with the absence of specific reimbursement pathways, hinders their adoption in practice. However, even adequate funding cannot guarantee adoption due to the unpreparedness of healthcare providers and patients to utilize them. As these are new treatment approaches, health care providers and patients require more education and experience to fully appreciate the potential of DTx and to build trust in their value and quality.

It will be interesting to see how the national and EU-wide market access rules for DTx evolve. One thing is certain: the development needs to be swift, as technology once again outpaces legislators – this time, patients and healthcare systems are at stake.

1 Deprexis website: Available at: https://us.deprexis.com.

2 Moovcare: web-based follow-up care for lung cancer patients. Available at: www.moovcare.com/images/upload/articles/22112422023859.pdf.