DIGITAL THERAPEUTICS:
Where Technology Meets Healthcare

Content for this article was contributed by the EVERSANA Asia Pacific team

Digital health is growing rapidly across the world, supported by technologies that not only assist disease monitoring or prevention but can also reduce the healthcare burden.

Digital technologies have improved equity of access and enabled European patients to monitor and self-manage their health. It has improved efficiency, effectiveness and quality of patient care while also reducing costs. Wider adoption will shape a predictive, preventative, personalized and participatory healthcare ecosystem.

One arm of digital health is digital therapeutics (DTx), which are evidence-based therapeutic interventions driven by software programs. DTx are considered part of the solution for the rise in preventable chronic diseases and rising healthcare burdens. They are supported by the increased focus on preventive healthcare, improvements in the reimbursement structure for DTx and government initiatives to support technology.

Many pharmaceutical companies are acquiring, partnering and investing in DTx and are looking at which markets are most receptive to these new technologies. As markets differ widely in their regulation and popular reaction to this evolving sector, the priority of launch markets for DTx may look very different from that of conventional products.

Challenges in prioritization

Digital health is transforming rapidly, and each country has its own regulations that vary with respect to DTx regulatory readiness and data requirements. No accepted definition of DTx exists in many countries, resulting in no reimbursement structure.

There are many factors to assess in launching a new DTx, such as health coverage, indicated population, DTx regulations and data requirements, DTx reimbursement potential, business model options, price potential, competition and cost of entry. These factors all play a very crucial role in deciding market attractiveness.

In most regions, the market is still in its infancy due to lack of awareness and access to DTx programs, resistance from traditional healthcare providers, unstable payment models, lack of IT infrastructure, and financial and social constraints. However, governments see the potential benefits of DTx and are adopting and promoting digital technologies across the value chain.

Motivating patients to use DTx and building confidence in them is a major challenge. Many patients still rely on traditional diagnosis and treatment and are slow to adopt DTx. Limited information on publicly accessible domains restricts information flow and increases ambiguity for would-be DTx providers in developing an understanding of these markets.

Helping pharma prioritize DTx markets

In looking for ways to improve client and patient journeys, EVERSANA™ developed a market prioritization framework for a digital therapeutics (DTx) comparative study, considering what constitutes market attractiveness. To begin, the team mapped markets on two major parameters: market potential, and ease of entry and reimbursement. For one client, we used this framework to compare the U.S. with representative APAC and European countries, enabling our client to better prioritize distribution markets.

In most countries, DTx products are considered Software as a Medical Device (SaMD) and follow medical device regulatory pathways, requiring clinical data and therapeutic claims. Understanding each country's DTx regulatory readiness, reimbursement policies and data requirements is vital to estimating the cost of entry.

Competitive intensity is high, and the competitor set is rapidly evolving, often in partnerships and combinations. The major challenge is securing pricing and access, and an important decision is whether to use a B2B or B2C model. Almost all competitors go for B2C models, which usually are self-pay models with low likelihoods of reimbursement but require lower investments into clinical development. B2B apps offer scope for higher prices but come with the burden of generating clinical evidence of efficacy. Epidemiology, affordability and other economic parameters remain important in assessing each market's opportunity.

Promising DTx markets

EVERSANA developed a matrix of market potential versus reimbursement likelihood and plotted each country based on the factors responsible for market attractiveness for a particular DTx.

U.S. and European markets have higher market potential with higher reimbursement likelihood, especially as certain European countries come out ahead on DTx regulations. The U.S. has the highest market potential and is making progress in defining DTx regulations. U.S. payers will develop approaches as the need becomes more real. However, the business model choice is a key factor that impacts commercial potential.

In APAC, China has the highest patient pool but is complex in terms of reimbursement, regulatory requirement and data security. Other regulated Asian markets present relatively attractive affordability and reimbursement potential but with a smaller market. Japan is mature in terms of familiarity with digital technologies and is favorably disposed toward them. As the installed base of digital apps related to health grows and the ecosystem expands, greater trust will drive a higher adoption in this typically cautious market. However, the business models are still evolving and require deeper analysis.

DTx is here to stay

It is clear DTx is here to stay. In several therapy areas, including CNS and CV/metabolic, there are already successful applications in both B2B and B2C business models, mostly in Western countries. The U.S. has a large market, which is likely to develop rapidly, as well as strong technology and pharma industries. Europe is making good progress on regulations and pricing criteria, while in APAC there are markets that are early adopters but with smaller market potential as well as markets that require more work but offer higher rewards in the mid- to long term.

> "In APAC, China has the highest patient pool but is complex in terms of reimbursement, regulatory requirement and data security."