THE RISE OF DIGITAL THERAPEUTICS OPPORTUNITIES IN CHINA

EVERSANA™

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In the past year the growth of digital health technologies has seemingly skyrocketed with the pandemic; but even before the pandemic took hold, investors were examining the market for opportunities with the expectation of a permanent evolution toward digital in many aspects of healthcare.

One focus for investment is China, where digital growth has outpaced most of the western world in areas such as e-commerce. While such growth is exciting, business models that offer returns are less understood. EVERSANA is examining the Chinese market to understand more about its digital health evolution.

Analyzing China's Digital Health Progression

To do this, our team began by identifying a segment of interest to our healthcare clientele, which is digital therapeutic (DTx) products. Still relatively new, without many examples anywhere in the world, we defined such products as delivering evidence-based interventions to prevent, manage or treat a medical condition. This definition includes products that come with an advisory feature linked to a measurement system, which advises either a doctor (B2B) or a patient (B2C) and has clinical evidence.

The evidence-based DTx segment in China is at about $250 million, of which about 80% is B2C. These products are mostly domestic in origin and address chronic conditions, such as diabetes and hypertension, which offer large numbers of potential customers who are very likely familiar with internet-based information and shopping. However, the lack of any form of public reimbursement for these products slows their uptake, making B2B a more robust business model in the current market if appropriate products can be demonstrated.

In China, the National Medical Products Association (NMPA) is responsible for medical devices, using a tier-based certification system based on patient safety, identical to the U.S. and EU system. DTx-specific regulatory requirements are loose, and most DTx products are certified as "software as medical device" (SaMD) under Class II, which requires clinical evidence.

China is pursuing a digital health regulatory reform initiative, but it is focused on telemedicine. DTx companies are lobbying the government to direct a second wave of reform toward DTx, hoping to drive its required growth and expansion. In the meantime, EVERSANA's research yielded these insights of potential interest to market entrants:

- **The evidence-based DTx market in China is in the region of $200-250 million, including hospital-facilitated B2B products, pharma/med tech collaboration products and non-prescription-based B2C products.**
- **Without public reimbursement of DTx prescription-based B2C products, this model has been slow to take off. As a result, startups are looking for partners with deep products or relying on mass marketing campaigns, including social media.**
- **NMPA continues to pose significant regulatory hurdles to DTx, as requirements are formulated based on perspectives of conventional medical devices and data security. There is no digital-specific formulary or regulatory pathway. There are also no reforms in the immediate pipeline, nor any oversight planned for wellness-based products.**
- **The B2B and the B2C prescription-based models rely on effective communication with a network of key opinion leaders (KOLs) and the pharma/med tech industry. Chinese companies are advantaged in these areas, making partnership an option to consider for non-Chinese entrants.**

The Chinese government recognizes the potential of digital health to be the next growth frontier, as it declared in its 2020 vision statement. More funds should be made available to back initiatives in digital health, as current outgoings are reduced by value-based purchasing. Companies with an interest in this area should be developing their networks of KOLs and pharma/med tech companies while also keeping global partnership options in mind.

Schedule a meeting with one of our experts in the Asia Pacific region today!