NEW ZEALAND
FOREIGN AFFAIRS & TRADE
Manatū Aorere

FEBRUARY 2024

German Digital Health Market Update

MARKET INTELLIGENCE REPORT

Summary

Prepared by: New Zealand Embassy in Berlin, in consultation with NZTE Berlin.

- Germany has recently adopted new legislation to promote digitalisation within their healthcare market. The legislation should accelerate implementation of the 2023 Digitalisation Strategy for Health and Care including wider and faster uptake of electronic patient records, e-prescriptions, digital health applications and telemedicine.

- Germany is seen as a leader within Europe of digital health applications on prespcription that support the detection and treatment of illnesses. This new market continues to grow as the number of medical conditions covered, applications approved, and prescriptions, continues to increase.

- Germany is one of the largest health markets globally and these developments may create new opportunities for New Zealand businesses offering innovative digital healthcare solutions.

Report

Germany has a world-leading healthcare market and spends approximately 13% of GDP (€500 billion) on healthcare. Further to the October 2021 report and the adoption of a Digitalisation Strategy for Health and Care last year, the digitalisation of the German health sector has been progressing slowly but is set to accelerate.

This update reports on recently adopted legislation, and takes stock of the success of 'apps on prescription' in Germany to date. From 9-11 April 2024, Berlin will host DMEA, Europe's leading digital health conference and trade show, with more than 700 exhibitors and 16,000 attendees expected.

New legislation will boost the digitalisation of the health sector and access to data
In December 2023, the Federal Parliament passed two important pieces of legislation on digital health:

- The Digital Act will enforce a shift towards electronic patient records (ePA), which already exist in principle, but have hardly been used by patients (1%) due to an opt-in requirement. From 2025, ePA will be the new standard for all patients covered by statutory health insurance, unless they actively opt out. Physicians and hospitals will be required to actively enter all relevant data, such as medication, lab results or operation reports, which can then be accessible to patients and doctors, with the aim of improving the efficiency and effectiveness of treatment. The technical ePA specifications have already been drafted by the responsible German digital health agency (gematik) and will be finalised this year following a consultation process. Previous problems such as long loading times are also being addressed.
- In addition to this, e-prescriptions will be mandatory, and the Act provides for improved access and the creation of a digital medication overview as part of the ePA. The potential use of digital health applications is expanded to medium to high risk treatments (Class IIb of the EU's Medical Device Regulation) and the support of pregnancy. At the same time, a new requirement to measure and publish application-related performance has been introduced. Finally, telemedicine is promoted by removing the current 30% limit on the eligible volume of video consultations, as opposed to face-to-face consultations.
- The Health Data Use Act establishes a data access point for (pseudonymised) health data from various sources for use by stakeholders such as researchers, pharmaceutical companies or insurers. The eligibility of applications will be assessed on their intended purpose. Insurers may, under certain conditions, also use their data for the individual approach of insurees.

Overall, these changes represent a step change for the digitalisation of the German health sector.

Digital health applications: market uptake so far and identified challenges

Since 2020, digital health applications (DiGA) such as smartphone apps or web applications may be approved in Germany for the monitoring and treatment of diseases, and may be prescribed by doctors and covered by health insurers. Approval is granted by the Federal Institute for Drugs and Medical Devices (BfArM), which provides comprehensive information in English for businesses wishing to apply. A `fast-track procedure´ aims for a decision within three months of submission of the complete application. At the beginning of 2024, the DiGA directory lists 29 fully approved applications, and an additional 23 provisional listings. Medical conditions include mental illnesses, obesity, muscle and joint problems, as well as alcohol and smoking addiction. So far, most apps have come from Germany, but some foreign companies have also been successful, and the directory includes both well established manufacturers and start-ups. Other European jurisdictions are reportedly following and establishing similar approval and reimbursement schemes, such as France and possibly Austria.

Two recent publications provide valuable insights into this new market - the official annual report of the German National Association of Statutory Health Insurance Funds published in January, and a survey by the German Digital Health Association, published in December. In the first three years since the launch of DiGA, the eligible applications were activated (e.g. downloaded) more than 370,000 times, at a total cost of €113 million. In the third and most recent year alone, more than 200,000 activations were recorded at a cost of €67.5 million.

While the two publications share a common understanding of the DiGA concept and its uptake, they differ somewhat in their assessment of developments to date. The insurers see rising prices despite a growing number of initially provisional listings that have yet to fully demonstrate efficacy, although they concede that a growing number of DiGA are finally succeeding in demonstrating a positive impact on care. Digital health companies, on the other hand, consider the provisional listing pathway to be a success, creating "the basis for generating the necessary revenue to cross-finance the high costs of trials", to the benefit of start-ups in particular. They also call for a more favourable assessment of applications that combine digital technology with face-to-face support (hybrid care).

The latter publication also identifies a number of limiting factors providers may want to be aware of, citing other recent studies. Accordingly, DiGA still remains a rather new form of care not all German patients or doctors are currently familiar with, meaning they are still less likely to be prescribed. Access to a prescribed DiGA is also found to be restricted by barriers such as the need for an activation code provided by the health insurer, and general reluctance by individual insurers to pay.

What’s in it for New Zealand healthcare companies

With all of this, one of the largest healthcare markets globally is developing a healthcare ecosystem that should be a lot more receptive to digital solutions than in the past. This creates new opportunities for New Zealand businesses with state-of-the-art and tested digital health products and services. New Zealand Trade and Enterprise (NZTE) stands ready to provide further advice and support.

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