German Health Sector in transition: Challenges and opportunities for Medtech

Market Report

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Prepared by the New Zealand Embassy in Berlin

Rāpopoto – Summary

- The German medtech and digital health market is significant and growing, but cost pressure on the health system and new EU regulation pose challenges. The digitalisation of the entire sector is finally accelerating, impacting both demand and procurement processes.

Pūrongo – Report

New Zealand is Germany's third largest provider of imported oxygen and respiratory therapy equipment. This marks a stunning success in one of the world's largest health markets (Germany spends 12% of its GDP on health). Just a month before the world-leading MEDICA trade show in Duesseldorf, this report looks at the German medtech and digital health market.

The German health sector is a major branch of the economy, with medical care representing nearly €200 billion of gross value added. Imports of health products (pharmaceuticals, medtech etc.) have been growing over the past decade but – perhaps counterintuitively – declined last year (with operations postponed, fewer visits to the doctor due to fear of Covid-19 etc.). For this year, the German medtech industry expects a return to domestic market growth. 70% of German health expenditure continues to be covered collectively (insurers, government etc.), but private spending – for care, sports/wellness or digital health products – has been growing faster. Germany has traditionally been well equipped with hospitals across the country, but consolidation is ongoing with the number of hospitals and beds gradually declining over the years, whilst ambulant care is growing.

Growing cost pressure

Germany has been spending a lot on health (including during the pandemic), and thanks to a buoyant economy over the past decade, it has been able to do so. However, the outlook is sobering and there are growing calls for reform as a new Government is set to emerge following the September election. Public health insurers are reporting incurring deficits of several billion euros due to increased spending and have been warning that absent further financial Government support fees would need to increase. At the same time, many (in particular smaller) hospitals are reported to be facing insolvency. There have been calls to pro-actively consolidate the hospital landscape – favouring fewer, but larger, better equipped hospitals – and further reduce the number of beds across the country, but closures in particular in rural areas are unpopular. Further adding to the cost are a relatively high frequency of visits to the doctor and high margins enjoyed by pharmacies. German medtech companies are reporting growing pressure on their prices as their customers group together to procure jointly.

Efficiency gains are needed, and digitalisation could help

Against this background, the German health sector is seeking efficiency gains. Whilst digitalisation is itself a challenge, at the same time it is seen as offering an opportunity to help drive efficiency (besides improving the quality of care and treatment outcomes). A key focus has been on establishing a digital infrastructure and shifting to digital processes. Germany has been well behind on that front, but the pandemic and various regulatory initiatives have accelerated the transformation. An electronic patient file (ePA) has been successfully trialled and will now be rolled out, subject to the patient's consent. Online appointments have been boosted by the Government's Covid vaccination campaign, as has digitial vaccination certification. Telemedicine, including virtual consultation, has equally been promoted through Covid, a trend that is expected to continue. Challenges remain, however, such as the evolved and therefore complex existing IT infrastructure at hospitals or the necessary balance between data protection and data availability. Stakeholders are conscious that digitalisation does not automatically increase efficiency and at least initially comes at a cost. With this year's Hospital Future Act, the Government will invest €3 billion with a focus on hospitals' digitalisation and IT security.

Other trends are also worth mentioning. Germany has become a key market in Europe for digital health applications (DiGA), with approved apps on prescription now being covered – somewhat reluctantly – by health insurers. A separate, more privately funded trend, is the growing popularity of wearables and apps tracking wellbeing and activities. Overall, German medtech companies are observing a growing acceptance for digitalisation of the health sector, and accordingly more investment.

Regulatory challenges: implementing the EU's Medical Device Regulation (MDR) Regulation

The most pressing challenge for the medtech sector in Germany is the implementation of the European Union (EU)'s MDR Regulation, which applies since May this year. The German sector's discontent is palpable, with industry groups complaining about a "dramatic lack of capacity" with regards to the Notified Bodies, of which many have yet to be re-approved, and which need extra resources to undertake thousands of fresh conformity assessments (for the CE Mark) before the transition period ends in 2024. Some manufacturers afraid of the work and cost involved have reportedly already abandoned specific products. The Government observes that implementation is making good progress although further steps are necessary, noting also that many companies have yet to apply for re-certification and should not wait too long before the end of the transition period.

Conclusion: not an easy market, but one in transition, opening up new opportunities

Health budgets will be tight after Covid, but the pandemic has also increased political and public awareness for the importance of a state-of-the-art health sector. There should still be interest in, and funding for, new hard- and software, which promises more effective or efficient treatment (or prevention). And fortunately given difficult Covid conditions, digital distribution/remote selling and customer support is becoming more common and relevant in the German market.

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