

The Mobile Health Market in Germany

ISSUE 2017/2018

Demographic change and digitalization are creating new market opportunities for mobile health solution providers in Europe's biggest health economy. A thriving healthcare start-up scene, growing insurance provider partnership opportunities and a changing legal framework provide ideal conditions in a market set to grow to EUR 3 billion in 2017.

New Healthcare Opportunities

Germany is Europe's largest healthcare market. More than EUR 320 billion is spent on health annually (not including expenditure for fitness and wellness), with spending equivalent to 11.2 percent of total gross domestic product. According to the Federal Ministry of Economic Affairs and Energy, the German healthcare industry employs more than 6 million people. Another 4 million depend on this industry, so that every fifth workplace in Germany is connected to healthcare. The German economy is largely shaped by small and medium-sized enterprises. This holds also true for the medical technology sector, which provides a strong foundation for the success of mobile health ("mHealth") in Germany. Ninety-five percent of Germany's medical technology companies employ less than 250 employees.

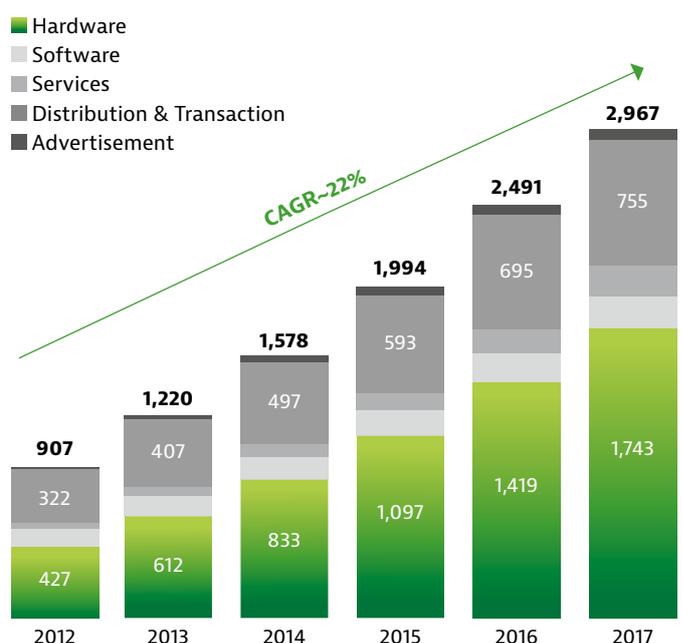
mHealth Market Potential

An aging population and the growth of chronic diseases are driving the demand for healthcare services. Combined with the increasing digitalization of society and increased fitness and health consciousness among the population, these factors are paving the way for mHealth solutions. Germany's mHealth market is extremely dynamic, with innovative methods of healthcare provision being discussed and new business models developed. mHealth also brings new players to the German healthcare systems, particularly start-ups who are generally seen as being the main drivers of mHealth. Conditions in the consumer health market are excellent. The willingness of Germans to invest in their well-being and investment in fast data networks offers excellent conditions for growth.

Market Segmentation

According to current forecasts, the German mHealth market will grow to around EUR 3 billion in 2017. Hardware is the largest segment of the mHealth market. Hardware sales account for 59 percent, over EUR 1.7 billion, of mHealth revenue. The hardware segment includes mobile sensors and medical devices that support monitoring. Such devices range from simple pulse meters to more advanced devices such as ECG vests that monitor heart rates. In both cases, data collected by these devices can be transferred to online fitness platforms or in real-time to doctors depending on their purpose.

mHealth Market Development 2012-2017 in EUR million



Source: A.T. Kearney 2013

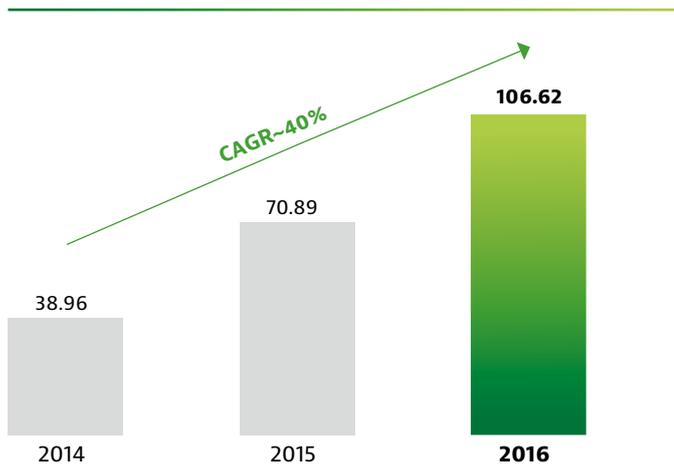
From Lifestyle Product to Medical Device

Out-of-Pocket Healthcare

Germany boasts a very promising out-of-pocket healthcare market. This vast market covers goods and services not paid for by insurers and includes everything from cough medicines and vitamin pills to wearable devices that monitor health indicators. According to the Roland Berger consultancy, the out-of-pocket sector is worth more than EUR 40 billion annually. On average, each adult in Germany spends EUR 900 on their health each year, this figure being over and above their monthly insurance contributions.

Fitness Tracker Revenue

in EUR million



Source: BITKOM 2016

Silver Economy

Already home to the highest proportion of over-65s in the European Union, Germany's over-65 population will increase to 24 million by 2035 – a seven million increase on the current 17 million. As such, over-65s will represent a third of the population – with people aged 50 years and older accounting for half of the population. Long neglected as consumers of private consumer goods and services, yesterday's senior citizens have become today's "golden agers" – the most important consumer group of the future. The net disposable income of married couples aged 65 and over currently averages EUR 2,440 per month. At present, the main customer segment is technically savvy people aged 20 to 45. This is bound to change as older people are introduced to the evident benefits of mHealth: reassurance through constant monitoring without doctor's visits, greater independence, and an increased chance of early diagnosis. Companies who establish a foothold in Germany's forerunner "silver economy" are well positioned to launch into European and international markets.

Consumer Market Opportunities

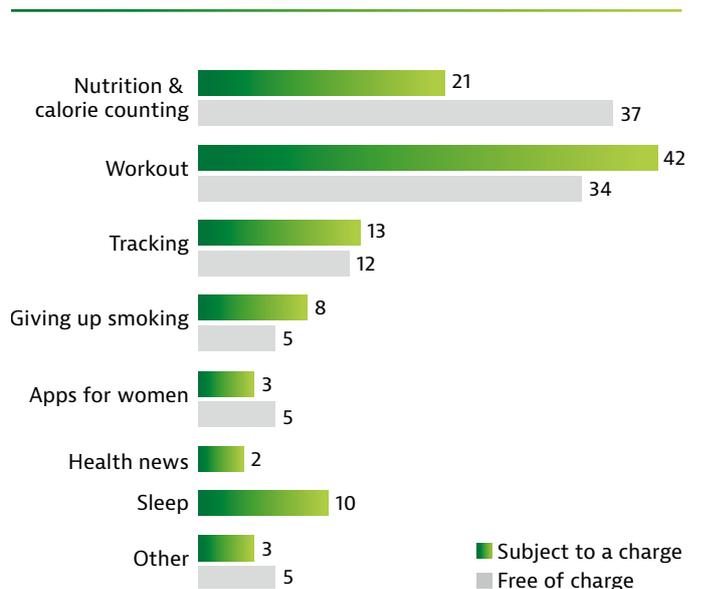
mHealth solutions in Germany enjoy widespread consumer acceptance, with fitness trackers, smartwatches and health and fitness apps growing in popularity. According to BITKOM, 31 percent of the German population uses fitness trackers to monitor their vital signs. Thirty percent of Germany's smartphone users install health apps that monitor vital signs, search for physicians and pharmacies, promote weight loss or help improve sleep patterns. The most popular health apps in Germany are those related to nutrition, calorie counting and physical exercise. The German market for fitness trackers has grown significantly in recent years: Revenue went from EUR 39 million in 2014 to EUR 107 million in 2016.

Professional Health Applications

At present, fitness trackers are typically used as lifestyle products. However, the great potential of such wearables and other mHealth solutions goes way beyond prevention and lies in patient medical care. The increased use of mHealth in the professional health sector will improve prevention and therapy adherence rates and, accordingly, help reduce hospital admission/readmission levels and doctor's visits. Adjustments to today's technological possibilities within the legal framework and the remuneration system will most likely result in a dramatic uptake in the professional mHealth market.

Health and Fitness Apps Downloads by Category 2013

in percent



Source: Statista, research2guidance 2015

Primary Healthcare Integration

Integrating mHealth into primary healthcare could see the mHealth market grow to EUR 4.2 billion by 2017. The main hurdle obstructing the proliferation of mHealth solutions in the professional health sector is the strict regulation of the German healthcare industry. Paradoxically, these stringent regulations help create a safer mHealth environment. Investors and health professionals are optimistic about the future of mobile health solutions in the primary healthcare sector. Cooperation between start-ups and health insurance companies is growing, with the legal framework taking shape and a number of health apps already in Germany's reimbursement scheme.

Fields of Application

mHealth solutions can be applied across the whole treatment path – from wellness and prevention to diagnostics and therapy. As such, mHealth links primary and secondary healthcare services and addresses current and future challenges in the healthcare system by contributing to the improvement of the quality of care and at the same time to the enhancement of efficiency. Monitoring is the key mHealth field of application across the treatment path. According to a study by PricewaterhouseCoopers, monitoring will generate 72 percent of mHealth revenue in 2017.

Apps as Medical Devices

Software applications or "apps" are just one of numerous mobile health solutions available today. They connect to sensors – such as bracelets and watches known as "wearables" – or medical devices to provide personal guidance system, health information and medical reminder services. They also enable the measurement of vital signs and make fitness and dietary recommendations. App usage scenarios are diverse

and range from simple fitness and wellness applications to complex programs for diagnostics and therapy purposes. Apps that are also intended for medical usage (e.g. heart rate monitoring via smartphone) can normally be classified as medical devices.

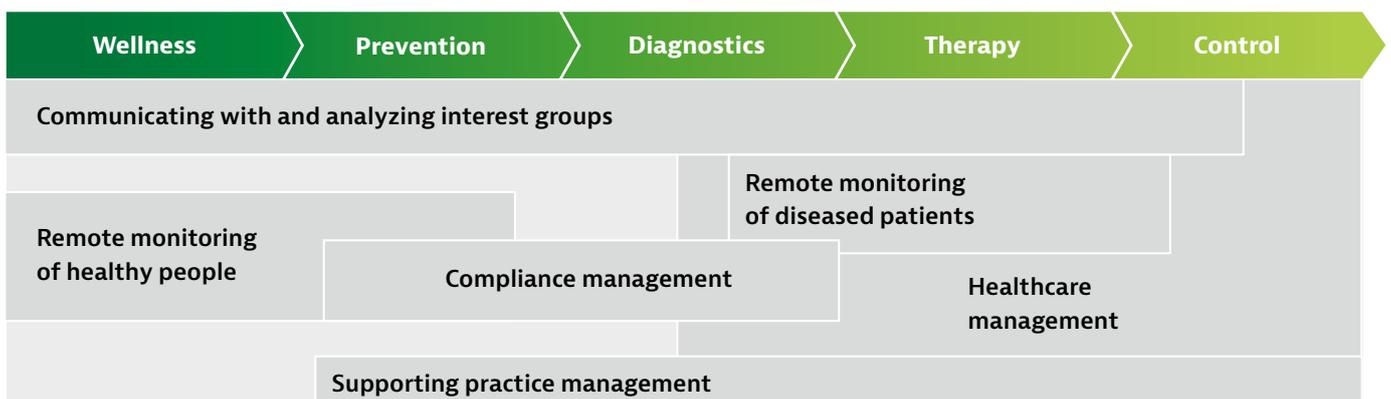
Medical Device Regulation

Stand-alone software and apps placed on the market as medical devices are subject to the same regulations as all other medical devices. Once considered medical devices, they have to be verified in accordance with EU guidelines and CE-marked. In Germany this classification is determined by the German Medical Devices Act (MPG) and European guidelines (more specifically, the Medical Device Directive 93/42/EEC). Medical devices are allocated to risk classes that range from Class I (low risk) and IIa and IIb to Class III (high risk). They are based on the possible harm that can be caused by a malfunction of the medical device. In vitro diagnostic medical devices and active implantable medical devices are the notable exceptions, being covered by separate directives.

App Categorization

The German approval body, the Federal Institute for Drugs and Medical Devices (BfArM), provides guidance on differentiation between fitness or wellness apps and medical apps (i.e. apps that are considered to be medical devices). When distinguishing between medical devices and health or fitness products, the decisive issue is whether they are intended for medical or non-medical use. This is defined by the product manufacturer. Decisions regarding the differentiation and the classification of an app are to be based on the intended purpose of the embedded software and are the responsibility of the manufacturer in agreement with a notified body.

mHealth can be applied across the entire treatment path



Software as a Medical Device

Any type of interference with data or information by stand-alone software is indicative of a classification as a medical device. Possible indicative terms in connection with the intended purpose of corresponding functions can be alarm, analysis, calculation, detection, diagnosis, interpretation, conversion, measurement, control, monitoring, and amplification functions. Indicative functions for classification as a medical device can be:

- decision support or decision-making software (e.g. with regard to therapeutic measures),
- calculation of dosing of medicines (as opposed to mere reproduction of a table from which users can determine the dosage themselves),
- monitoring patients and collecting data (e.g. by measurement if the resulting data has an influence on diagnosis or therapy).

Software is a medical device

Stand-alone software (e.g. smartphone app) can be classified as a medical device if the software is intended by the manufacturer to be used for humans and for at least one of the following purposes:

- diagnosis, prevention, monitoring, treatment or alleviation of disease;
- diagnosis, monitoring, treatment, alleviation or compensation of injuries or handicaps, investigation, replacement or modification of the anatomy or of a physiological process;
- control of conception.

Examples

- **Decision supporting software:**
Software that is intended to give healthcare professionals recommendations on diagnosis, prognosis, monitoring or treatment of an individual patient.
- **Software systems:**
The system is subject to medical device legislation if the entire system is qualified and it consists both of software with and without the properties of a medical device.
- **Telemedicine software:**
Communication systems for telemedicine can either be non-medical devices, if they are only intended for transfer of data or a combination of non-medical devices and medical devices.
- **Picture Archiving and Communication System (PACS):**
Where the PACS software is intended to control a medical device or have an influence on its use or allow a direct diagnosis, this would support its classification as a medical device.

Software is not a medical device

These functions of stand-alone software do not result in classification as a medical device:

- mere provision of knowledge,
- pure data storage,
- archiving,
- lossless compression,
- communication,
- simple search functions.

Examples

- **Operating system software**
(e.g. Windows, Linux)
- **Software for general purposes**
(even where used in connection with healthcare)
- **Software or apps as health or fitness products:**
Software or apps intended for sporting activities, fitness, well-being or nutrition without a medical purpose are generally not to be classified as medical devices.
- **Hospital Information Systems (HIS):**
HIS can be combined with other modules including medical devices. HIS that only support patient management are generally not medical devices (e.g. collection of data for patient admission, administration of general patient data, scheduling of appointments, insurance and billing functions).
- **Picture Archiving and Communication System (PACS):**
Where the PACS software is only meant for storage or archiving of pictures and not for diagnostic purposes, this would indicate that it is not a medical device.

Supporting Business Success

Excellent Workforce

More than 80 percent of the German workforce is in possession of an academic degree or has received formal vocational training. The country's dual education system – unique in combining the benefits of classroom-based and on-the-job training over a period of two to three years – is specifically geared to meet business needs. Recruitment services are actively supported by government agencies. Germany's major metropolitan regions – Berlin, Hamburg, Munich, Cologne, Frankfurt (Main), and the Ruhr region – attract young and highly educated people from across Europe. The resulting multilingual labor pool makes Germany an attractive base for rolling out business to other European countries.

Diversified Education in Medical Technology

Academic training in the medical technology sector in Germany is of the highest quality. In order to maintain and enhance the country's excellent medical technology R&D standards, key skills in engineering and natural sciences – and especially in information technology – are taught in medical technology training. Knowledge transfer and the continuous flow of researchers between public and private research institutions is one way of staving off the shortage of emerging young academic talent. In recent years the total number of students in German universities has been increasing, as has the share of students in natural sciences and engineering.

World Class Know-How

While Germany is home to the largest population of researchers in Europe (22 percent of all EU scientists live and work in Germany), German scientist work on projects all over the world. The research results obtained by the Max Planck Society, for example, are archived through fruitful partnership with some 5,400 partners in research institutions in over 100 countries. Cooperation projects between companies and academic research institutes provide an efficient way to close knowledge gaps. Scientists can be easily integrated into the company team of developers and researchers and, increasingly, institutes provide for the necessary laboratory facilities.

Start-up Friendly Environment

There has been a digital boom in Germany resulting in the emergence of start-up hubs in the country's major cities. The cost of living is relatively moderate in Germany, compared to other developed countries. The availability of co-working spaces, local networks and numerous industry events help to create a vibrant digital ecosystem which also contribute to make Germany an attractive investment proposition for start-ups and healthcare companies alike.

Dual Education System: Apprenticeship



Source: Germany Trade & Invest 2015 (based on: DIHK, Federal Ministry of Education and Research, Federal Statistical Office 2013)

Sound and Secure Legal Framework

According to the World Economic Forum, Germany is one of the world's best locations in terms of planning and operating security. Germany is also one of the world's leading nations in terms of intellectual property protection and protection from organized crime. German regulatory authorities are highly professional in their operations. The German legal system also counts as one of the world's most efficient and independent. Social, economic, and political stability provides a solid base for corporate investment projects. Contractual agreements are secure and intellectual property is strictly protected in Germany.

First Choice Business Location

Ernst & Young's "European Attractiveness Survey 2016" confirms Germany's reputation as one of the most attractive business locations in the world. International decision makers ranked Germany first within the EU. A substantial 69 percent of the more than 700 international managers surveyed named Germany with their personal to three ranking, making Europe's top country for foreign direct investment (FDI). The A.T. Kearney FDI Confidence Index 2016 confirms Germany's reputation as the most attractive business location in Europe, further ranking Germany fourth worldwide. The country can be found in the top five FDI markets among respondents in all three sectors included in the survey – industry, services, and IT – being particularly strong in the IT sector.

OUR SERVICES

About Us

Germany Trade & Invest (GTAI) is the foreign trade and inward investment agency of the Federal Republic of Germany. The organization advises and supports foreign companies planning to expand into the German market and assists German companies seeking to enter foreign markets.

Investment Location Germany

GTAI provides close-to-market information to international companies looking to enter German markets. Our specialist industry teams prepare all of the relevant information essential to business success in Germany. GTAI's comprehensive range of information services includes:

- Market and industry reports
- Market entry analyses
- Business and tax law information
- Business and labor law information
- Funding and financing information

Business Location Services

GTAI supports international companies from market entry to business start-up in Germany. Expert project teams advise and assist in the business establishment phase. GTAI's range of free services includes:

- Legal and tax-related project support
- Funding and financing advisory services
- Site visit organization
- Local partner and network matchmaking
- Public and private partner coordination

All investment-related services are provided entirely free of charge. Our specialist industry teams have hands-on experience in their respective industries and treat all investor enquiries with the utmost confidentiality.

Imprint

Publisher

Germany Trade and Invest
Gesellschaft für Außenwirtschaft
und Standortmarketing mbH
Friedrichstraße 60
10117 Berlin
Germany
T +49 30 200 099-555
F +49 30 200 099-999
invest@gtai.com
www.gtai.com

Executive Board

Dr. Jürgen Friedrich, Chairman/CEO
Dr. Robert Hermann, CEO

Editor

William MacDougall,
Germany Trade & Invest

Author

Chemicals & Healthcare Team:
Julia Pietsch,
julia.pietsch@gtai.com

Layout

Germany Trade & Invest

Print

Kern GmbH, 66450 Bexbach
www.kerndruck.de

Picture Credits

Front page:
gettyimages/suedhang

Order Number

20902

Notes

All rights reserved ©Germany
Trade & Invest, February 2017

Reproduction, in whole or in part, only permissible with express prior authorization. All market data provided is based on the most current market information available at the time of publication. Germany Trade & Invest accepts no liability for the actuality, accuracy, or completeness of the information provided.

Supported by:



on the basis of a decision
by the German Bundestag