

What is mhealth and what is it good for?

- What is mHealth?
- What are wearables?
- What are Health Apps?
- How many individuals use Health Apps?

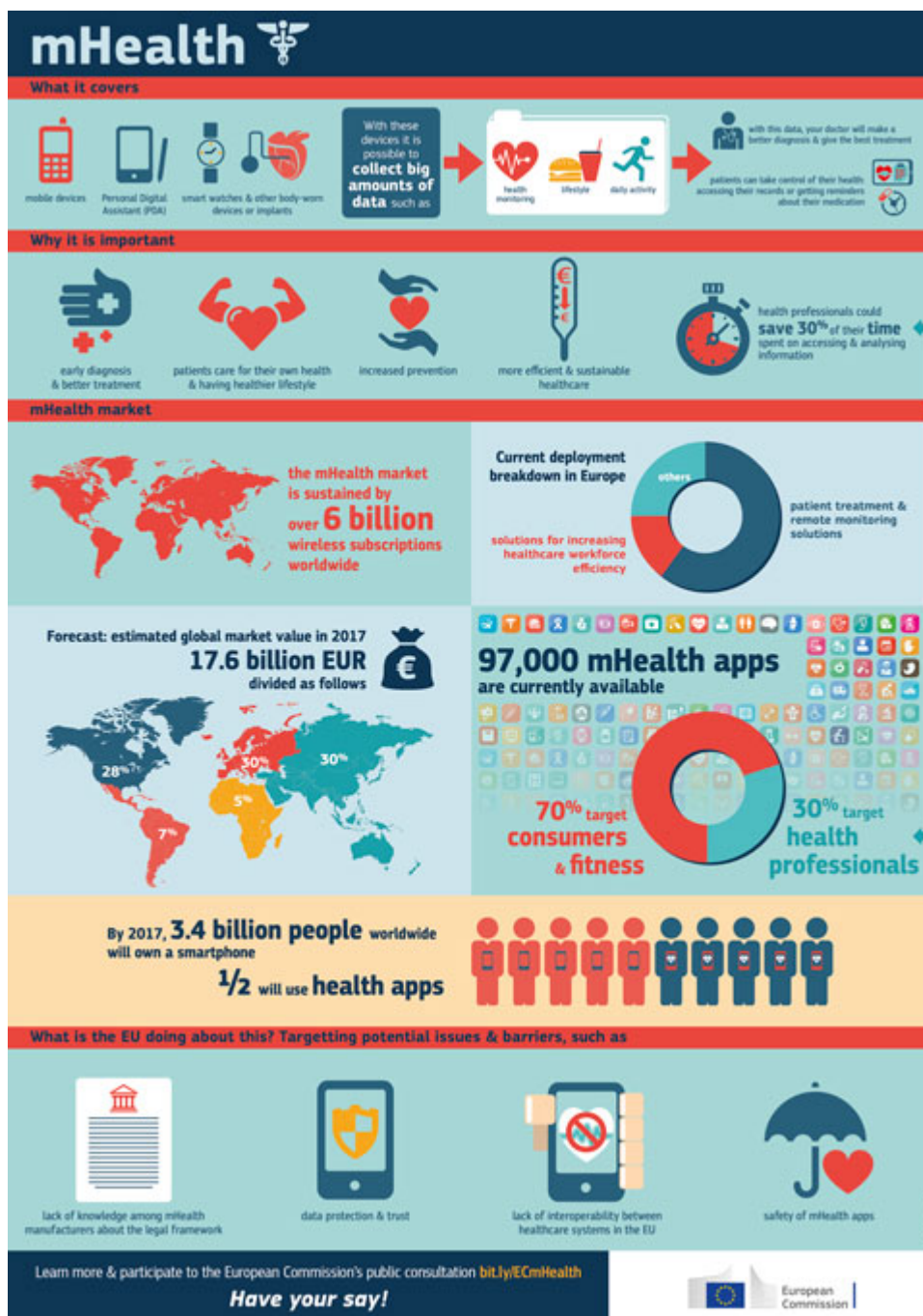
What is mHealth?

mHealth is an abbreviation for mobile health technology, or more precisely: mobile and wireless technologies to support the achievement of health objectives¹. Definitions for mHealth vary. We follow this one: “Medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDAs), and other wireless devices”¹.

Examples for mHealth are: Diabetes monitoring sensor and/or app; wrist band monitoring the heart beat rate; an app that provides health advice after typing in physical or psychological symptoms. Many wellness- and fitness-apps are categorized as “health apps” (and accordingly as mHealth) in the app stores. These can range from step counting apps, over calorie intake monitoring and personal fitness training technology (for example wristband in combination with an app).

What are wearables?

Wearables are technical devices that can be worn on the body. They are designed to measure and record certain health-related parameters electronically. These parameters can, for example, be the number of steps, the heart rate or the duration and depth of sleep. So-called wearables include fitness wristbands, smart watches and all other technical devices which are worn on the body and can collect body data. A distinction can also be made between wearables, which store and play back the measured data locally on the device itself, and wearables, which can pass on the data to third parties, for example via an app.



Source: <https://ec.europa.eu/digital-single-market/node/69592>

What are health apps?

So far, there is no uniform definition for health apps. However, we can generally say that health apps are standalone software, i.e. pure software without associated hardware. This can be purchased through the app stores, for example. A distinction can be made between different types of health apps. Apps with medical device features include decision support software, software systems, telemedical software, hospital information systems (HIS) and image archiving systems (PACS). Simply put, the term 'medical device properties' is used when the App is used in the healthcare system. Decision support software is primarily used by medical professionals to support diagnosis, prognosis, monitoring or treatment of patients. Telemedical software is software that enables the attending physician to monitor and evaluate

patient data via telecommunications. Telemedical services can be used for pure data transfer, but also, for example, for diagnostic support. In addition, there are apps that are not categorized as medical devices, but are still related to health. These can include apps that are used as fitness or wellness products, if they fall within the broad range of health promotion and prevention. According to the German Federal Institute for Drugs and Medical Devices (BfArM), the classification of apps is the responsibility of the respective manufacturer.

“The decision regarding the delimitation and classification, which is to be carried out on the basis of the concrete purpose of the software, as well as the corresponding placing on the market is incumbent in each case on the manufacturer (responsible person according to § 5 MPG), if necessary in coordination with a notified body”²

If the manufacturer wants his/her product to be declared as a medical device, it is possible for him/her to submit an application to the BfArM. The BfArM provides guidance on classification on its website. According to these guidelines, apps that are used exclusively for sports, wellness or nutrition purposes are not software with medical device features (and therefore are not subject to the legal regulation of such products), but are nevertheless health apps.^{1 2 3 4}

How many individuals use health apps?

Almost every second person living in Germany uses health apps, and numbers are increasing. According to the online survey “EPatient Survey 2017”, the use of coaching apps (Apps with advisory and supportive character) and online second opinions is rapidly increasing. Clinically evaluated services, such as specific apps for asthma, depression or cardiovascular diseases, are less well known than commercially available services.

1. https://www.bfdi.bund.de/SharedDocs/Publikationen/Faltblaetter/Gesundheitsapps.pdf?__blob=publicationFile&v=5 ↑
2. https://www.bfarm.de/DE/Medizinprodukte/Abgrenzung/MedicalApps/_node.html ↑
3. <https://ec.europa.eu/digital-single-market/node/69592> ↑
4. <https://ec.europa.eu/digital-single-market/en/news/summary-report-public-consultation-green-paper-mobile-health> ↑