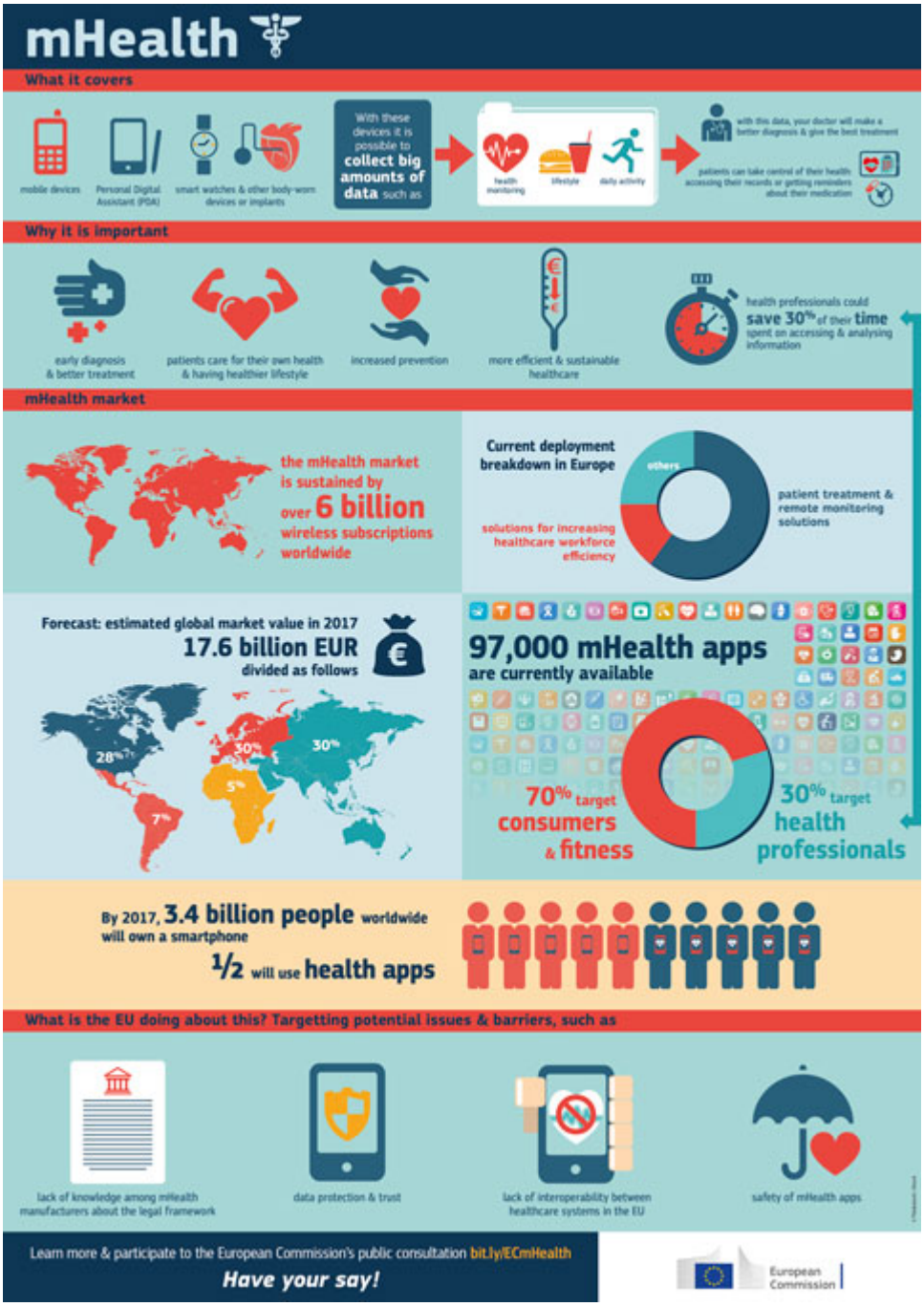
What is mhealth and what is it good for?

What is mHealth?

mHealth is an abbreviation for mobile health technology, or more precisely: mobile and wireless technologies to support the achievement of health objectives. 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].
Some random examples of mHealth are: diabetes monitoring sensor and/or apps, wrist bands monitoring the heart beat rate, ingestible drug adherence sensors and apps that provides health advice after typing in physical or psychological symptoms. In addition, 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, to calorie intake monitoring and personal fitness training technology (for example a wristband in combination with 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 their product to be declared as a medical device in Germany, it is possible for them 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]

What are wearables?

Wearables are portable devices, usually worn on the body, that can generate, exchange and process data. Think of fitness wristbands, smart watches and all other technical devices which are worn on the body or clothes and can collect body data such as, for example, number of steps, heart rate or the duration and depth of sleep. A distinction can also be made between wearables that store and play back the measured data locally, typically on the device itself, and those that can pass on the data to third parties, for example via an app. Smartwatches for example not only offer some of the functions of a smartphone, like messaging or controlling connected devices such as bluetooth speakers, they are also equipped with various sensors that can measure bodily functions. As sensors and processors get smaller and more powerful, they can be integrated into different kinds of items: glasses and shoes for instance, or materials like textile. These developments expand the possibilities to use technological devices close to the body, or even implanted in the body. Although the functions of wearable technology can be diverse, the close proximity to the body makes this type of technology particularly relevant for health and fitness purposes.

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 ↑