Applying Swiss law to the mobile health app sector

As in many jurisdictions, the rise of health and fitness-related apps on smart devices has led to opportunities for developers and pharmaceutical companies in Switzerland. Here, Dr. Lorenza Ferrari Hofer and Phillip Schmidt of Pestalozzi Attorneys-at-Law consider the application of Swiss law to such medical apps, and discuss a number of hurdles for involved parties to navigate, including around in-app advertising and data protection requirements.

The massive adoption of smartphones and tablets and the growth of applications running on such devices has literally put a wearable health database into the hands of consumers. Smartphones and tablets include various sensors, such as cameras, microphones, gyroscopes, GPS, etc., which allow for unprecedented access to the movement and behaviour of the users of these devices. App developers, pharmaceutical and medical devices companies, and increasingly users have realised the potential of such devices for monitoring health in various ways.

Health and fitness-related apps, from simple step counters to sophisticated diagnostics tools for the exclusive use of healthcare professionals, are on a steady growth path. In recent years, pharmaceutical companies have discovered health and fitness-related apps for themselves and are increasingly developing them for various purposes. They hope to gather various digital health data. Once the pharmaceutical companies acquire such data, which often includes the sensitive personal data of patients, it serves various ends, such as for market supervision or even for clinical research purposes. Big data analysis for clinical research is still in its infancy but is already shaping up to be revolutionary for scientific advancement despite some of its jarring shortcomings, such as reliability of data and reproducibility.

The growing prevalence of apps in the Swiss healthcare sector poses various challenges from a legal point of view that will be addressed in the following article. Major challenges include data protection issues and regulatory questions, such as Switzerland's very strict rules on advertising for patients and on CE conformity of medical devices.

Apps as medical devices

Giving medical apps a legal qualification is challenging, since no generally accepted definition exists. For the purpose of this article, we refer to an app as any program or piece of software performing a specific task and running on any platform or via a website. We understand medical apps as apps that perform a function that is connected to the body and/or the health of a human being. Examples of medical apps are step counters, BMI calculators, medication dosing calculators, medication reminders, medical encyclopedias in an app, tools for healthcare professionals for choosing a therapy together with their patients, etc.

The Federal Act on Medicinal Products and Medical Devices ('TPA') defines medical devices in Article 4 *inter alia* as software that is intended to have a medical use and the principal effect of which is not obtained by a pharmaceutical. Therefore, all medical apps that are not just simple step counters, encyclopedias or diaries are considered medical devices and therefore are subject to the rules of the TPA. In particular, the developer must be able to prove that the app has been submitted to a CE conformity assessment and the assessment has shown that the app is safe and fit to provide the advertised technical and medical services (Article 46 of the TPA).

Data protection rules apply

Any app that processes personal data, including storing personal data, must do so in accordance with the Swiss Federal Act on Data Protection ('FADP'). Personal data refers to data of an identified or identifiable natural or legal person. Sensitive personal data refers *inter alia* to data on the health of a person (Article 3 of the FADP). Consequently, gathering any health data of Swiss consumers via a medical app that is tied to an identifiable person requires the prior and transparent information of the data subject and any processing of such data by third parties requires the data subject's explicit consent (Article 4 of the FADP). For example, if the pharmaceutical company would like to use personal data from the app for advertising or research purposes and/or transfer it to the US, the data subject must consent to such uses. Such consent is regularly obtained within the terms and conditions of the app that must be accepted before the app can be used. An online 'I accept' consent is a valid one under the FADP.

Limited in-app advertising

The TPA and its Federal Ordinance on Advertising Medicinal Products ('OAMP') as well as industry codes, such as the Code of Conduct of the Pharmaceutical Industry in Switzerland ('Pharma Code') and the FASMED Code of Business Conduct, prohibit pharmaceutical and medical devices companies from advertising to patients their

prescription products and those of their products that must be exclusively administered by healthcare professionals (Article 32 of the TPA and the above-mentioned codes of conduct). Only the advertising of specific products is prohibited and therefore, general image advertising by the pharmaceutical or medical devices company is permitted. Companies may advertise such products, however, if they are exclusively targeted at and exclusively visible to healthcare professionals.

Any medical app including information on specific pharmaceutical products or medical devices (with the exception of the package insert) may not be accessible to patients, unless patients are to use such apps together with their doctors. Consequently, pharmaceutical companies offering a medical app must clearly define their target audience and accordingly choose the content of the app. If such app includes information on specific pharmaceuticals, such app cannot be accessible to patients or to the public in general.

Medical apps as material benefits

Article 33 of the TPA prohibits pharmaceutical companies from offering, promising or granting material benefits to healthcare professionals that dispense or prescribe pharmaceuticals in order to induce them to buy, prescribe, recommend or dispense pharmaceuticals.

If a pharmaceutical company provides a medical app for free to healthcare professionals, such app may be considered a prohibited material benefit. This can be avoided in different ways: (i) if the medical app is of very low value, it may not qualify as a prohibited material benefit; (ii) if the medical app is provided in exchange for a service (e.g. data gathering via the app), the app would no longer be considered a material benefit, since there is a *quid pro quo* exchange; and finally (iii) if the app is not provided to healthcare professionals that prescribe/dispense pharmaceuticals (e.g. the app is provided to accountants in a hospital) and consequently there would be no danger of inducing any healthcare professional to buy, prescribe, recommend or dispense pharmaceuticals.

The developer must be able to prove that the app has been submitted to a CE conformity assessment and the assessment has shown that the app is safe and fit to provide the advertised technical and medical services

Any offering of app services considered as material benefits must be openly disclosed by the pharmaceutical companies, both in respect of their receivers and in respect of their value (Article 271 Pharma Code).

Liability for apps' use

Generally, developers include various disclaimers in their medical apps for excluding their own liability in the use of the apps by healthcare professionals and especially by patients.

With regard to certain liability risks, a disclaimer, which is explicitly accepted by the app user (e.g. by clicking on an accept button), may be valid. This may be the case for liability risks from some contractual damages. However, liability for regulatory obligations and liability for bodily injury, death, and for gross negligence and fault cannot be validly disclaimed under Swiss law (Article 100 of the Code of Obligations). In addition, product liability may apply if a defective medical app causes bodily injury, death or damage to property (Article 1 of the Federal Act on Product Liability).

Digital data ownership

Since the digital data collected by the health and fitness-related apps have scientific and economic value, in particular as part of health databases (big data), the question arises as to who the owner of such data is and who can use them and for what purpose. Swiss law does not provide for specific rules on the ownership and use of digital health data and essentially the involved partners, including the data subjects, are free to conclude any agreement. As far as data subjects give their prior informed consent, providers of health and fitness-related apps can become owners of the digital health data and use them for their own purposes and share them with third parties in the pharmaceutical industry and in the research sector.

Summary

If a pharmaceutical or medical devices company decides to provide a medical app to Swiss patients or healthcare professionals, several legal implications must be considered and addressed.

In particular, with regard to the recent surge of medical apps and the according spike in interest from the regulatory authority Swissmedic, it is highly advisable to carefully assess any potential implications and address them before publishing the app. If not, dire consequences both from a regulatory and from a liability point of view are a realistic possibility for any developer of medical apps.

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