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Latest Legal Developments on Fitness and Health Apps

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Key Take-aways

1.
Fitness and health apps raise questions regarding their legal qualification. An update to a Swissmedic guideline clarifies when software qualifies as medical device.

2.
Marketing claims provided by the apps as much as their functionalities play a key role in setting the applicable legal framework.

3.
Developers must carefully consider the functionalities and content of fitness and health apps from the early stages of their development.

1 Introduction

Over the past two decades, the **health sector** has undergone significant technological developments. The ubiquity of digital devices in our daily lives, combined with the ongoing democratization of developments in artificial intelligence (AI), has opened the door to new possibilities. **Fitness and health apps**, which increasingly tend to incorporate AI functionalities such as chatbots, as well as fitness and health coaches, illustrate this trend. Depending on their functionalities, these apps may enable end users to record medical information (e.g., records of medication intake), automatically track health metrics (e.g., sleep quality, heart rate frequency and blood oxygen saturation), assess their health condition and/or make decisions (e.g., on therapy, diet, training sessions or recovery).

While these developments open up new market opportunities for health and technology professionals, they also raise a number of **legal and regulatory challenges** which, if not properly anticipated, may expose operators to regulatory enforcement as well as civil liability and criminal proceedings.

Whether these risks materialize, and which obligations apply in practice, depends on the regulatory framework encompassing, in particular, medical device law, advertising rules and data protection law.

New technology blurs the line between consumer software and medical device.

2 Legal framework

The Federal Act on Medicinal Products and Medical Devices (**TPA**), as well as the Medical Devices Ordinance (**MedDO**), form the cornerstone of the regulatory framework governing apps as medical devices. Largely aligned with the European Medical Devices Regulation (EU-MDR), the MedDO defines what a medical device is and regulates the legal consequences of such a qualification.

The TPA, its implementing ordinances as well as the Federal Act on Unfair Competition (UCA), outline the requirements applicable to advertisement related to fitness and health apps, depending on performance claims or promotional statements that they make, and their use by healthcare professionals.

Irrespective of their qualification as medical devices, these apps involve the processing of personal data, including sensitive personal data relating to health. They may also, depending on their functionalities or settings, result in profiling activities, automated decision making and/or cross-border disclosure of personal data. Accordingly, developers must design them so that they comply with the applicable data protection regulations.

Finally, developers of fitness or health apps have to closely monitor the quickly evolving landscape on AI regulations. In a press release dated 12 February 2025, the Federal Council has announced its intent to continue its activities regarding the regulation of AI in specific sectors such as the health sector, and to adopt sector-specific provisions on AI where necessary.

3 Qualification as a medical device

One of the threshold regulatory question for fitness and health apps is whether they **qualify as medical devices**. This determination triggers the application of specific regulatory obligations. These include conformity assessments, registration of medical devices in databases (e.g., swissdamed and/or EUDAMED), drafting of a technical documentation as well as establishing and maintaining a quality management system. Furthermore, medical devices are subject to regulatory surveillance. In Switzerland, surveillance will be carried out by the Swiss Agency for Therapeutic Products (Swissmedic).
It is, therefore, critical to assess whether a fitness or health app qualifies as a medical device. According to Art. 3 (1) MedDO, software may qualify as medical device if the three following **conditions** are cumulatively met:

- It is intended by its manufacturer to be used for human beings;
- It does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but may be assisted in its function by such means; and
- It serves to fulfil one or more of the specific medical purposes listed in Art. 3 (1) (c) MedDO, such as diagnosis, monitoring, treatment or alleviation of a disease, an injury or disabilities, respectively investigation, replacement or modification of the anatomy or of a physiological or pathological process or state.

While the assessment of the first two requirements generally does not raise any particular issue, determining whether an app serves a medical purpose can prove to be complex.

Qualification of an app as medical device triggers strict regulatory obligations.

On 21 April 2026, Swissmedic published an updated version of its information sheet on medical device software. This guidance clarifies that a software qualifies as a medical device *"if it is intended to be used, alone or in combination with another product, for a medical purpose for the benefit of an individual (and not solely for the benefit of a population) and if the processing of medical data is not limited to storage, archiving, simple search, communication or lossless compression"* (see section 4 p. 5). For instance, while apps limited to the mere logging of information do not qualify as medical devices – meaning that they simply replace the maintenance of paper health data records –, those displaying medical images of a specific individual for medical purposes qualify as medical devices as they go beyond serving as data records (see section 4 p. 5). Qualification of apps containing nudging functionalities (e.g., reminders to take medicines, indication of the next injection site, etc.) can be ambiguous and should, therefore, be assessed on a case-specific basis.

The information sheet also states that the **purpose** designated by the manufacturer, whether on the label, in the instructions for use or in promotional or sales materials or statements or in the clinical evaluation, is decisive for the software qualification as medical device (see sections 3.1 and 4 p. 5).

However, in light of the general principles of good faith and the prohibition of the abuse of rights, mere statements such as *"This app is not a medical device"* are unlikely to allow manufacturers to circumvent their regulatory obligations in situation where the app functionalities actually serve medical purposes.

Consequently, health or fitness apps developers should carefully assess the effects of the planned functionalities and ensure compliance with the regulatory requirements before placing them on the market. Failing to comply with regulatory obligations applicable to medical devices may constitute a criminal offence.

4 Advertising

Qualification as a medical device is not the only factor attracting regulatory scrutiny. The manner in which a fitness or health app is **presented and marketed** may also give rise to legal obligations, particularly where the app is associated with a medicinal product or makes claims regarding therapeutic benefits.

The TPA and the relevant implementing ordinances (e.g., the MedDO respectively the Ordinance on the Advertising of Medicinal Products (**OPuM**)) specifically regulate **advertising activities** related to therapeutic products.

The distinction between permissible information and regulated advertising is, therefore, of particular importance. The OPuM defines advertising of medicinal products as any form of information, promotion, or inducement intended to encourage the prescription, dispensing, sale, consumption, or use of medications (Art. 2 (a) OPuM), whereas general information on health or disease does not fall within the scope of the OPuM.

Accordingly, manufacturers should carefully assess whether a statement is limited to neutral educational content – such as factual and objective information or general scientific data related to health or diseases – or whether it contains references which directly or indirectly create an association with a specific medicine and, therefore, may be considered as advertising. The statements must comply with the requirements on transparency of promotional statements, mandatory information and, if applicable, obligation to obtain prior authorization by Swissmedic (see also Swissmedic's guidelines on advertising on the Internet).

App functionalities and statements play a key role in the legal setting.

The TPA subjects advertising activities to different rules depending on their **target audience**. While advertising exclusively directed at persons who prescribe or dispense medicinal products is in principle permitted, the advertising of medicinal products supplied on a prescription to the public is prohibited. The TPA further prohibits other forms of unlawful advertising, such as promotion activities which are misleading or contrary to public order and morality, or which may incite an excessive, abusive or inappropriate use of medicinal products.

Where an app qualifies as a medical device, the advertising rules applicable to medical devices must also be taken into account.

For instance, the TPA enables the Federal Council to restrict or prohibit the advertising of certain medical devices and enact regulations concerning cross-border advertising in order to protect health and prevent fraud. On this basis, the Federal Council has enacted provisions on advertising, according to which claims for devices must only contain statements that correspond to the product information and must not enclose misleading statements, particularly concerning the intended purpose, the safety and the performance of a device.

As with medicinal products, the MedDO also distinguishes between advertising to the general public and advertising to healthcare professionals. Medical devices which are intended solely for use by the latter must not be advertised to the public.

From a practical perspective, developers should, therefore, carefully review the content of their fitness and health apps, as well as any associated websites, social media content and marketing materials, to ensure that statements concerning therapeutic products and the apps themselves remain compliant with the applicable advertising rules.

5 Conclusion

The rapid development of digital health technologies, increasingly enhanced by AI functionalities, is reshaping the delivery of healthcare and creating new opportunities for innovation. If an app qualifies as a medical device, the manufacturer is subject to numerous regulatory requirements.

As a result, from the early design stage onwards, developers must carefully assess whether their products qualify as medical devices, comply with applicable data protection requirements and respect the regulatory framework governing advertising and promotional activities.

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