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Software as a medical device – Swiss Federal Administrative Court confirms fertility tracker app is a medical device

In a recent decision, the Swiss Federal Administrative Court (FAC) confirms that a mobile application intended to monitor fertility qualifies as a medical device used for contraception subject to a certification procedure with a notified body. This ruling confirms the alignment of the classification of contraception apps between Swiss and European authorities.

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1. Facts

The subject of this case was an interpretive mobile application that analyses women's menstrual cycle using the symptothermal method, in order to provide natural birth control (the "App").

On February 5, 2020, Swissmedic prohibited the marketing of the App, considering that it lacked a valid CE marking. Swissmedic held that, because of its contraceptive purpose, the App was a Class IIb medical device (under the then applicable law), which required a conformity certification from a notified body.

On March 3, 2020, the developer of the App appealed this decision with the FAC, arguing that the natural contraceptive method offered by the App presents no risks and cannot be equated with other methods of contraception. Accordingly, the appellant requested the classification of the App in Class I (for devices that do not involve a notified body in the conformity certification). In a previous landmark decision Sympto C-669/2016 of September 17, 2018, the FAC qualified the same App as a medical device, despite the developer's argument that the App was a mere educational tool.

2. Classification of a birth control app

According to the Medical Devices Ordinance ("MedDO"), medical devices are classified in Switzerland in accordance with the classification rules applicable in the EU.

In this new decision C-1256/2020, the key question was whether software can be "used for contraception" within the meaning of Rule 14 of Chapter III of Annex IX of Medical Device Directive (EU) 93/42/EEC (hereafter "Rule 14"), in force at the time of the disputed decision. Such software are now addressed in Rule 15 of the new EU legislation, see below, III). The FAC also needed to consider whether natural methods of birth control – such as the symptothermal method used by the App – are comprised within the notion of "contraception".

Pursuant to Rule 14, all medical devices used for contraception belong to Class IIb, unless they are implantable or long-term invasive devices, in which case they belong to Class III.

According to the FAC, this provision unequivocally covers all medical devices used to prevent pregnancy or facilitate conception, regardless of the nature of the medical device or the method of birth control. The FAC emphasizes that the intended purpose of the medical device (i.e. control of conception) is the only criterion to decide whether a classification in Class IIb is justified.

Therefore, insofar as an app may be used for birth control, it shall be classified in Class IIb. The placing on the market of such software thus implies its certification by a conformity assessment body.

This new interpretation constitutes a landmark decision in the classification of fertility tracker apps. In its former practice, Swissmedic denied the application of Rule 14 to software, on the grounds that software cannot mechanically protect from pregnancy, as opposed to traditional methods of contraception. This distinction led Swissmedic to classify fertility apps as a method of birth control in Class I instead of Class IIb. With this new precedent, the FAC overruled the former criterion, holding that the lack of a physical contraceptive protection is irrelevant.

It is worth noting that in its reasoning, the FAC does not refer at all to the former classification practice of Swissmedic. Instead, the FAC merely states that Rule 14 is perfectly clear and leaves no room for interpretation (which remains questionable given the former interpretation of Swissmedic).

3. New applicable rules

As mentioned above, the FAC decided this case under the former provisions of the MedDO and EU Directive 93/42/EEC, which were in force at the time of the disputed decision.

However, it is noteworthy that this change in the classification practice with regard to contraception apps occurred in the context of the revision of the MedDO and EU medical devices legislation.

The revised MedDo entered into force on May 26, 2021, along with the new EU Medical Devices Regulation 2017/745 ("EU MDR"). This revision introduced special provisions regarding the classification of software (see Chapter III of Annex VIII of EU MDR – directly applicable in Switzerland via Article 15 MedDO).

In this context, the question arose as to whether software used for contraception should be

classified pursuant to Rule 11 (dedicated to software as medical devices) or Rule 15 (dedicated to contraceptive devices, i.e. the former Rule 14).

It was clarified in 2019 by the Medical Device Coordination Group that software used for contraception are governed by Rule 15, leading to their classification in Class IIb (MEDICAL DEVICE COORDINATION GROUP, MDCG 2021-24 : , Guidance on classification of medical devices, p. 48 and MDCG 2019-11: Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 – MDR and Regulation (EU) 2017/746 – IVDR, p. 14.).

These clarifications represented the opportunity for Swissmedic to align its interpretation of the notion of "used for contraception" with the interpretation of the EU authorities.

Considering the non-binding nature of the EU guidance on classification (although usually followed by Swiss authorities and courts), this new interpretation endorsed by the FAC removes the uncertainty left around the classification of fertility apps in Switzerland and confirms the alignment with the EU practice.

Please do not hesitate to contact us in case of any questions.

Legal Note: The information contained in this Smart Insight newsletter is of general nature and does not constitute legal advice.

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