



St. Gallen, 28 September 2018

Press Release

regarding judgment C-669/2016 of 17 September 2018

“Sympto” app considered to be a medical device

An app designed to measure the fertility of the woman using it by analysing personal data is considered to be a medical device, and must be evaluated in order to make sure that it conforms to the necessary standards before being sold in Switzerland, the Federal Administrative Court (FAC) has ruled.

The “Sympto” application aims to accurately pinpoint periods when the woman using it is or is not fertile and is to be used for contraceptive purposes or when planning to get pregnant. To do this, the app uses data provided by the user such as her body temperature and cervical mucus (the symptothermal method). In March 2016, Swissmedic, the Swiss authority responsible for the authorisation and supervision of therapeutic products, banned the app from coming to market as it had not been tested to verify its conformity to the necessary standards.

A medical device...

Swissmedic has argued that the app is a medical device as it calculates a window of fertility for each user after they have provided the system with their personal data. The app therefore needs to comply with the legal requirements set out for these kinds of devices. These requirements vary depending on the risks that the medical device may pose.

... or an educational tool?

The SymptoTherm Foundation has disputed this decision before the FAC, arguing in particular that its app should not be classed as a medical device but rather as an educational tool, such as a book or a standard accounting program.

The FAC issues its approval

In its judgment, the FAC discusses the use of the app and how it handles data. It firstly notes that the app is intended to be used for *medical* purposes. The app is indeed designed to allow the users to control their own contraception/efforts to conceive, or at least to pinpoint their physical state according to ‘symptoms’, in other words it offers a diagnostic result regarding the medical matter of conception. The medical use is also presented as such on the device’s website. Secondly, the FAC states that the app processes and interprets the personal data of each user to inform them of the various stages of fertility in their cycle. This means the app can be defined as a *device* which carries out an action based on data. The app must therefore be treated as a medical device which

must undergo testing to check that it conforms to the provisions of the Therapeutic Products Act and the Medical Devices Ordinance. The FAC therefore approves Swissmedic's decision and rejects the appeal.

This judgment may be appealed to the Federal Supreme Court.

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About the Federal Administrative Court

Located in St. Gallen, the Federal Administrative Court (FAC) was established in 2007. With its staff of 357 employees (307.65 FTE) and its 76 judges (68.2 FTE) it is the largest federal court in Switzerland. The Federal Administrative Court has jurisdiction to hear appeals against decisions rendered by Swiss federal authorities. In specific matters, the FAC may grant review on decisions rendered by cantonal authorities. Recourse actions are also reviewed by the Court. The FAC is composed of six divisions. It renders an average of 7,500 judgments every year.