SPICE ROUTE
LEGAL

PERIOD TRACKING APPS: ARE THEY MEDICAL DEVICES?
AN INDIAN PERSPECTIVE

I. MENSTRUATION TRACKING APPS

Menstruation or period tracking apps are widely used by menstruators across geographies to maintain a tab on their menstrual cycles. These apps allow the users to chart their periods and provide predictions about menstruation or fertility. Many apps offer additional features and functionalities, including notifications about ovulation cycles, enhanced period predictions, detailed cycle analyses, customer support, and personalised health support.

Some of these apps also offer suggestions on hormonal imbalances and irregular cycles, offer health information, and suggest lifestyle changes based on the symptoms recorded by their users. In addition to functioning as trackers, the wide variety of these offerings also allow users to avoid or attempt pregnancy and identify potential health issues.

These solutions have evolved beyond just standalone apps: one provider operates its period tracking solutions through a texting function. While different controversies, including privacy and regulatory risks, have begun to arise globally in respect of these apps, their market in India continues to boom. However, this gives rise to a pertinent question: do these apps, considering the health-related assistance that they provide, fall within the scope of laws on medical devices?

II. MEDICAL DEVICES UNDER THE INDIAN LAW

Medical devices in India are governed by the Drugs and Cosmetics Act, 1940 and the Medical Devices Rules, 2017 ("**Medical Devices Rules**"). A medical device includes a software that is intended by its manufacturer to be used specially for human beings which, in addition to other purposes, may assist with (a) diagnosis, prevention, monitoring, treatment or alleviation of any disease or disorder, or (b) control of conception. Several compliance aspects, including classification, registration, import, labeling, sales, and post market requirements apply to medical devices.

III. PERIOD TRACKING APPS AS MEDICAL DEVICES

Most period tracking apps permits users to log data about their menstrual cycles as well as provide predictions on the next estimated date of their period, ovulation date, and the dates of high and low fertility. Typically, these functionalities enable and assist users in planning or avoiding pregnancy. Essentially, these apps act as digital contraceptives for the users. Given that the functions offered by these apps fall within the control of conception, it is likely that several apps may be categorised as medical devices under Indian law.

The functionalities of these apps play a key role in determining how the Medical Devices Rules would apply. Certain apps permit users to log their moods and symptoms and use such data to provide information on hormonal imbalances, suggest lifestyle changes, and flag potential underlying health conditions. Some apps

go a step further and use machine learning to offer features that enable users to assess their risk of polycystic ovarian syndrome. Other apps have begun to partner with researchers to share data that would assist with research on breast cancer. These are examples of how additional functionalities may also contribute to such apps falling outside the scope of the "control of conception" aspect of the definition of medical devices, but providing assistance with the diagnosis, prevention, monitoring, and treatment of a disease, ensuring that these apps continue to be classified as medical devices.

IV. THE PROBLEMS AND THE WAY FORWARD

While period tracking apps offer multitudes of features that can aid menstruators in understanding their monthly cycles, the wide variety of features offered by them including details about aiding or avoiding pregnancy, flagging health problems, and suggesting lifestyle changes bring into question whether any studies have been conducted by the apps to determine the accuracy of their health risk assessments. The consequences of these could range from missed diagnosis due to overreliance on the app to overdiagnosis.

While meeting the compliance requirements that would apply in respect of medical devices may be an entry barrier, requiring businesses to comply with regulations on testing, medically approved algorithms, cybersecurity requirements, and permissible use of data and insights derived from such data may be a welcome move to ensure a responsible industry.

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For any queries, please reach out to tech geeks at Spice Route Legal: