

The Use of Cannabis in Pharmaceuticals and Medical Cannabis Cultivation in Türkiye

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Cannabis (*Cannabis sativa* L.) is a psychoactive plant that has been used since ancient times. It contains more than 500 components and 103 identified cannabinoids. The main compounds in the plant are tetrahydrocannabinol ("**THC**") and cannabidiol ("**CBD**"), the former with and the latter without psychoactive effects.

The limited licensed use of cannabis, however, dates to the late 1990s in the US, where it was used only for scientific research. Since 2000, there has been a burgeoning increase in the legal adoption of the plant by more countries, especially for medical purposes.[\[1\]](#)

Over the past two decades, as scientific research into the therapeutic benefits of cannabis advanced, more compelling evidence has been produced about the potential of cannabis in the treatment of diseases such as cancer, epilepsy, Parkinson's, multiple sclerosis ("**MS**"), Alzheimer's and Huntington's. This major development has played a crucial role in convincing lawmakers to recognize the necessity of cannabis production and use for medical purposes.

History of Cannabis Regulation in Türkiye

The publication and enforcement of the Regulation on the Cultivation and Control of Cannabis to Produce Active Pharmaceutical Substances ("**Regulation**") on 13.09.2024 has initiated a renewed discourse on the utilization of cannabis in the medical industry. Although the Regulation is a milestone for the use of cannabis in medicine, cannabis has already been regulated in a number of laws and international conventions to which is Türkiye is a party.

Under Article 3 of Law No. 2313 on the Control of Narcotic Drugs ("**Law**"), dated 24.06.1933, the cultivation, import, export, and sale of cannabis were prohibited. Cultivating cannabis without a license is punishable by imprisonment, and THC has been regulated as a narcotic substance under Turkish law. The Turkish Penal Code No. 5237 imposes severe criminal penalties, including imprisonment, for the use, trade, and possession of cannabis.

Türkiye is also a party to international agreements, including the Single Convention on Narcotic Drugs of 1961, which it joined in 1967 (amended in 1972) and the United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances (1988), both of which reinforced restrictions on the use of cannabis. The listing of cannabis as an illegal drug in the 1970s made the restrictions even more severe.

In 1990, however, an amendment to the law called Regulation on Hemp Cultivation and Control allowed the cultivation of hemp, a type of cannabis, for industrial purposes such as the production of fiber, seeds, and stalks, with permission from the Ministry of Agriculture and Forestry.

The amendment in 1990 and an updated regulation in 2016 were major steps towards the industrial use of hemp but neither addressed its cultivation for the production of "active pharmaceutical substances." The aforementioned regulation focussed only on the production of industrial products, and the production of active pharmaceutical ingredients were excluded from this scope.

Another attempt at regulating the production and industrial use of hemp came in 2019 when the Turkish Ministry of Agriculture and Forestry published The Report and Action Plan for Industrial Hemp Cultivation in Türkiye^[2]. But it was on 23.03.2023 and with an amendment to Article 23 of the Law that the initiatives that focused on hemp cultivation in Türkiye took a major shift in direction. The amendment explicitly included "cannabis cultivation for the production of flowers and leaves for the production of pharmaceutical active ingredients," thus creating a legal basis for cannabis cultivation for the purpose of producing active pharmaceutical ingredients. Also, the General Directorate of the Turkish Grain Board ("**TMO**") was authorized to oversee and license limited cannabis cultivation and processing for this purpose, granting TMO the right to authorize real or legal entities for production.

The efforts aimed at hemp and cannabis regulation eventually culminated in the publication and entry into force of the Regulation on 13.09.2024. It is the first legal regulation explicitly regulating the production of cannabis as "an active pharmaceutical ingredient." Such attempts at further regulation of cannabis in Türkiye are expected to continue later in 2024 and 2025.

Scope of the Regulation

The Regulation basically addresses two main uses of cannabis: i) obtaining pharmaceutical active ingredients; and ii) controlled and fit-for-purpose use by licensed institutions/organizations for scientific research purposes.

In accordance with the Regulation, real or legal persons wishing to engage in cannabis cultivation must apply to TMO between October 1- 31. The applicants are required to submit a detailed production plan and a Letter of Commitment, as stipulated in the Regulation.

Applicants are also expected to submit an updated supply protocol signed with the company to which the active pharmaceutical ingredient will be sold, in which the specifications and quantity of the ingredient are stated. They will be notified by December 31 whether their application has been successful. The number of authorized candidates is determined by the office of the President of Türkiye. Successful applicants must also receive a permit for their manufacturing site from the Turkish Medicines and Medical Devices Agency ("**TITCK**") within 18 months and apply to TMO to obtain an authorization certificate. TMO will then issue cultivation permits which will be valid for 5 years. The start and end of the validity will be specified in the certificate. It is forbidden for people without a permit to produce cannabis.

Universities, research institutions affiliated with the Ministry of Agriculture and Forestry and organizations with a research license do not need to obtain cannabis cultivation authorization to produce cannabis-based active pharmaceutical ingredients for the purpose of scientific and R&D studies. However, these studies must first be authorized by the Ministry of Agriculture and Forestry, where their appropriateness will be examined based on TMO requirements.

To conduct clinical trials with the active pharmaceutical ingredient obtained from cannabis cultivation, it is mandatory to obtain separate authorization from the Ministry of Health.

The Regulation also specifies requirements for production facilities, measures to prevent the illegal production of cannabis, as well as procedures and principles regarding harvesting, processing, export and sale of cannabis. For example, legally produced cannabis can only be sold to real and legal persons authorized by the Ministry of Health.

If the product is intended for export, an export permit from the Ministry of Health is required. This permit is granted in exchange for an import permit issued by the competent national authority in the importing company's country, as recognized by the United Nations International Narcotics Control Board ("INCB").

The Ministry of Agriculture and Forestry, the Ministry of Interior and the Ministry of Health have been assigned to resolve any doubts arising from the implementation of the Regulation.

Current Status and Forecasts

Pursuant to Law No. 2313, narcotic substances included in the Single Convention on Narcotic Drugs can only be produced, imported, exported, possessed, sold and purchased with the permission of the Ministry of Health. In this context, according to the Communiqué on the Monitoring of Imports of Substances Requiring Authorization from the Ministry of Health, tetrahydrocannabinol (THC), the primary compound in cannabis, is listed among the active substances subject to special authorization.

In addition, based on the limited definition in the Single Convention on Narcotic Drugs, which defines hemp as the upper flower or fruit part of the cannabis plant (excluding seeds and leaves when not accompanied by upper parts), hemp seeds are not covered by the legal prohibitions and hemp oil is freely available for sale in Türkiye.

There are no licensed medicines with CBD and/or THC active substances in Türkiye yet. Currently, CBD and THC are in the list of foreign active substances subject to red prescription and special written authorization of the TITCK.

Although the number of approved cannabis-based products is few and far between, more and more European countries are adopting legislation allowing the medicinal use of cannabis and there is increasing support for such use from health professionals and researchers.

Recent developments reveal that the use and cultivation of cannabis for medicinal purposes is slowly but surely advancing in Türkiye. With the legalization of cannabis production, it is expected that the licensing of cannabis-based medicines will materialize and the procedures for their licensing and placing on the market will be aligned with the European Union, with which Türkiye has close trade relations. It is also expected that new and more comprehensive regulations will be developed by both the Ministry of Agriculture and Forestry and the Ministry of Health to meet the needs as the cannabis production for pharmaceutical purposes begins in the coming days.

[1] https://www.incb.org/documents/Narcotic-Drugs/Technical-Publications/2018/INCB-Narcotics_Drugs_Technical_Publication_2018.pdf

[2] <https://tgsd.org.tr/turkiyede-endustriyel-kenevir-yetistiriciligi-raporu-eylem-plani-toplantisi-katilimi-26-mart-2019/>

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