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Italy Reclassifies Natural CBD Oil As Medicine Containing Narcotic

by [David Ridley](#)

Italy reclassifies natural CBD as a narcotic drug. The decision may see challenges from companies marketing in Italy natural CBD supplements registered in other European countries, given that the European Court of Justice (CJEU) overturned a similar position taken by France in 2020.

As of today, products containing natural cannabidiol (CBD) intended for oral use are classed in Italy as narcotic drugs.

Following a decree issued on 7 August 2023 – entering into force on 20 September and adding CBD to Italy’s list of narcotic and psychotropic substances – such products can only be dispensed through pharmacies and with a medical prescription.

Furthermore, the advertising of such products to the public is prohibited, and the manufacture, storage and distribution of them will require prior authorization.

“The decree applies, essentially, to oils containing natural CBD,” explains Mauro Turrini, counsel at international law firm Bird & Bird. “Other types of CBD products, including in principle oils used in cosmetics [i.e. CBD not for oral use] and oils containing synthetic CBD [i.e. CBD not from extracts of cannabis] should not be impacted by the decree.”

May See Legal Challenge

Currently in Italy, oils containing natural CBD are sold in regular shops for “technical uses” – i.e. uses not involving oral consumption – and in pharmacies.

Unless something changes in the immediate future, for example the Italian Ministry of Health introduces further rules/clarifications or the decree is successfully challenged in court, oils containing natural CBD intended for oral use will no longer be sold in regular shops and when

sold by pharmacies, they will be treated as medicinal products containing narcotics, Turrini notes.

Legal challenges may come from companies marketing natural CBD oils in Italy that are legally registered in other countries as food supplements, on the basis of the principle of free movement of goods within the European Union.

“If this happens, it will be up to the Italian authorities to defend the lawfulness of the decree by demonstrating that the restrictions imposed by the decree are actually necessary and proportionate for the purpose of protecting the public health of Italian citizens, as required under the Treaty on the Functioning of the European Union,” Turrini points out.

CJEU Decision

There would be a precedent for such a legal challenge. In 2020, the European Court of Justice (CJEU) overturned a French court’s decision to ban a vape containing natural CBD marketed by Kanavape in the country, but registered in the Czech Republic, on that basis that it was a narcotic drug and a risk to public health.

The CJEU concluded that CBD extracted from the whole plant was not a drug within the meaning of the UN Single Convention on Narcotic Drugs given that “CBD does not contain a psychoactive ingredient in the current state of scientific knowledge.” (Also see "[Highest European Court Rules CBD Is Not A Narcotic Drug](#)" - HBW Insight, 23 Nov, 2020.)

The CJEU decision prompted the European Commission to scrap its “preliminary view” that CBD extracted from the flowering and fruiting tops of the hemp plant (*Cannabis sativa* L.) “should be considered as a narcotic.” (Also see "[European Commission Decides CBD Is Not A Drug Opening Up Novel Food Pathway](#)" - HBW Insight, 3 Dec, 2020.)

Revealing its change of heart in an email to industry players that had their novel food applications placed on hold during the summer, the Commission stated, “In light of the comments received from applicants and of the recent Court’s judgment in case C-663/184, the Commission has reviewed its preliminary assessment and concludes that cannabidiol should not be considered as drug within the meaning of the United Nations Single Convention on Narcotic Drugs of 1961 in so far as it does not have psychotropic effect.”

CBD Applications Still Paused

“As a consequence,” the Commission continued, “cannabidiol can be qualified as food, provided that also the other conditions of Article 2 of Regulation (EC) No 178/2002 are met.”

Unfortunately, the European Food Safety Authority has since paused all CBD novel food applications after its panel on Nutrition, Novel Foods and Food Allergens (NDA) raised concerns

about the ingredient's safety. (Also see "[EU CBD Novel Food Applications On Hold As EFSA Considers Health Risks](#)" - HBW Insight, 15 Jun, 2022.)

The decision to pause the 19 applications followed a literature review by the NDA which identified “significant” potential adverse effects relating to a number of human systems, including liver, gastrointestinal tract, endocrine system, nervous system, psychological well-being and reproduction.

Whether Italy’s decision has any effect on EFSA’s position “remains to be seen,” Turrini said.

“It’s hard to tell right now,” he Turrini said. “However, a possible impact might be strengthening the position of those who believe that thresholds should be established to distinguish between CBD products which are classified as food and CBD products which should be classified as medicines.”