Cultivation and medicinal use of *Cannabis sativa L* in Brazil

Camila Martino Parise
Pinheiro Neto Advogados, São Paulo
cparise@pn.com.br

Júlia de Castro Kesselring
Pinheiro Neto Advogados, São Paulo
jkesselring@pn.com.br

The medicinal use of *Cannabis sativa L* and its derivatives is already authorised in many jurisdictions around the world.

In Brazil, *Cannabis sativa L* is included in the list of plants that, as a general rule, cannot be cultivated, harvested, exploited, imported, exported, traded, extracted, handled or used. These activities are typified as criminal conduct. An exception is made for the cultivation and harvest of the plant for scientific or medicinal purposes, under certain restrictions and upon authorisation of the Ministry of Health.

In the past, the substances derived from *Cannabis sativa L*, tetrahydrocannabinol (THC), which is the psychoactive compound of the plant, and cannabidiol (CBD), were also listed as prohibited substances under Brazilian regulation.

In 2014, based on certain evidence of CBD's efficacy in relieving the symptoms of patients suffering from debilitating conditions such as epilepsy and Parkinson's disease, Brazilian patients pressured the National Public Health Agency (Agência Nacional de Vigilância Sanitária (ANVISA)) to authorise the direct importation of drugs containing THC and CBD. ANVISA was reluctant to issue such authorisations, which lead patients to claim in court the right to import the product.

Several debates involving the medical community, patients and public authorities on how the bureaucracy and lengthy procedures for importing CBD-based medicines were harming patients caused ANVISA to change the Brazilian regulatory framework for the medical use of drugs containing substances derived from *Cannabis sativa L*.

ANVISA first included *Cannabis sativa L* in the list of medicinal plants. Subsequently, ANVISA reclassified CBD from a prohibited to a controlled substance grounded on scientific studies showing that CBD could be used for therapeutic purposes and technical data demonstrating that the use of CBD was not associated with chemical dependence. By considering CBD as a controlled substance, ANVISA allowed the registration of medicines with CBD as the active ingredient.

ANVISA also authorised the prescription of drugs, approved or not in Brazil, containing THC and CBD, and defined specific criteria and procedures for individuals to directly import, on an exceptional basis, certain CBD-based medicines, in association with other cannabinoids, including THC.

Despite the evolution of the regulation above, currently, there is only one THC and CBD-based product approved by ANVISA as a specific medicine. The majority of products containing such substances are still imported directly by the patient under a medical prescription and special authorisation from ANVISA.

Based on the fact that there is only one medicine approved by ANVISA, the current discussions around the medicinal production of *Cannabis sativa L* and its substances rely on the interpretation of the exception provided in Brazilian legislation, which admits the cultivation and harvest of *Cannabis sativa L* for scientific and medicinal purposes, but is silent as to whether such an exception covers the extraction, manipulation and commercialisation of the plant and its substances.

Because the exploitation and trade of the plant and its derived substances are not expressly covered by the legal permission, and cultivation authorisation is granted only for a specific period, companies that are willing to invest in the production of *Cannabis sativa L*-based medicines have faced challenges in setting up their activities in Brazil.

Currently, there is precedent by which an association of patients was authorised to cultivate *Cannabis sativa L*, extract its oil and deliver it to the associated patients. In general terms, the decision was grounded on the interpretation that the current regulation already authorises the cultivation and manipulation of *Cannabis sativa L* for medical purposes and is a measure necessary to achieve the right to health provided for in the Federal Constitution.

ANVISA, in the records of the aforementioned legal case, stated that the regulation of the activities related to *Cannabis sativa L* should be treated with caution because any activity may potentially

be channelled into unlawful purposes, and it would be necessary to establish rules on good planting practices, the control of access to sites, the form of prescription to patients and the management of information. Establishing rules for the importation and cultivation of controlled plants is included in the ANVISA agenda. The agency is working on the draft of a new regulation that will allow the importation of prohibited plants and substances by legal entities, such as *Cannabis sativa L* and THC, respectively, under specific conditions, but it is not possible to predict how long it is going to take for the new regulation to come into effect.

In the legislative sphere, three bills of law – still in the preliminary phase of discussion – are running in the Brazilian Congress. Their purpose is to authorise the importation of plants and seeds of *Cannabis sativa L*, and decriminalise its production and cultivation for personal therapeutic purposes at a quantity necessary for treatment, only by producers authorised by ANVISA.

Therefore, although Brazilian legislation admits the registration, prescription and use of drugs produced with *Cannabis sativa L* in Brazil, and ANVISA is currently working on a new regulation that will allow the importation of *Cannabis sativa L* and THC in Brazil, the local production of medicines using plant-extracted substances is still under debate and depends on regulatory improvements that are expected to be included in the list of priorities of the governmental authorities.