

O ESTADO DE S. PAULO

Anvisa proposal for cannabis regulation for medicinal use

The Brazilian regulatory agency Anvisa will present for public consultation a proposal to authorize the cultivation and production of cannabis in the country for medical and scientific purposes; currently the agency authorizes the importation of plants for research purposes or for use by the pharmaceutical industry.

André Borges, O Estado de S. Paulo

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Cannabis can only be cultivated by companies or legal entities authorized by Anvisa.

Photo: REUTERS/David McNew



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What is the current regulation in Brazil?

Production or commercialization of the marijuana plant (cannabis) in Brazil is prohibited. Anvisa only authorizes the importation of plants for research purposes or for use by the pharmaceutical industry.

Is there production of cannabis-based medicine and its derivatives in Brazil?

There is only one marijuana-based drug authorized in the country. Mevatyl, which is approved in 28 countries under the name Sativex, is indicated for patients who suffer from spasticity as a result of multiple sclerosis. One package costs, on average, R \$ 2,500.

Is there domestic production of cannabis-based remedies in Brazil?

Currently, legislation prohibits such production, but patients, associations and some companies in the sector have obtained legal authorization to plant and produce marijuana and its derivatives.

What is Anvisa proposing?

Anvisa is proposing to hold two public consultations to discuss the safety and control requirements to allow the cultivation of marijuana for medical and scientific purposes and to evaluate the current requirements for authorization of cannabis products in Brazil.

Is there a legal provision?

The possibility of allowing cultivation for medicinal purposes is provided for in Drugs Law 11.343 / 2006 and Decree 5.912 / 2006. Brazil is also a signatory to a 1961 United Nations agreement that already provided for the possibility of planting cannabis for medicinal purposes.

Can anyone plant marijuana?

No. Cultivation can only be undertaken by companies or legal entities authorized by Anvisa.

Can patients using cannabis extracts or interested associations produce it?

No. No individual can produce marijuana, even for medical or research purposes. The associations that want to produce it will have to become legal entities and go through Anvisa's accreditation process.

Does Anvisa's authorization allow licensed companies to produce marijuana for recreational use?

No. Anvisa's proposal is to authorize production for medical or scientific purposes only.

Besides Anvisa, will the federal police need to authorize marijuana production?

The company will not have to request special authorization from the federal police or any security agency for the production of cannabis. However, Anvisa has notified that it will forward to the federal police, during the licensing process, an opinion request in regard to the security measures for the installation, such as its location. The owners and technical directors of the company will have to file attestations of a clean criminal record.

Where can marijuana be planted?

Anvisa proposes that production be restricted to closed and controlled environments. It cannot be produced in an open environment, such as a farm or greenhouse, and the location cannot be revealed by the placement of signs and other identifiers .



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The building will be required to have a double door system, with automatic interlocking closure. Walls, vents, doors, ducts and dividers must be constructed with durable materials. The windows should be sealed with double glazing. The security system must be maintained 24 hours a day / 7 days a week throughout the production cycle, including at all entry points along the perimeter and the windows, ducts and openings. The whole environment will be controlled by biometric access.

In case of unauthorized access to the building where planting is to take place, what will the company be required to do?

Companies will have up to five consecutive days to inform Anvisa of any incident but must report it immediately to police authorities.

Can the plant be sold in its natural state?

Yes. The plant can be commercialized in its natural state since it is intended for research institutions, manufacturers of pharmaceutical inputs and manufacturers of medicines.

Can an ordinary individual buy the plant?

No. Individuals and associations that are currently authorized to produce derivatives will not be able to purchase the plant. In addition, no distributors of marijuana for the pharmaceutical industry will be allowed. Any sale will have to be direct between the producer and the authorized sector. Compounding pharmacies are also prohibited from receiving the plant and its derivatives.

Who can produce medications?

Only companies registered with Anvisa for this purpose or that obtain special authorization. Currently, ten national and international companies in the sector have already shown interest.

Will companies be able to produce any kind of medicine?

No. Only medicinal products based on cannabis, its derivatives and synthetic analogues, for which therapeutic indication is restricted to patients with severe, debilitating diseases and/or life-threatening conditions without existing therapeutic medical alternatives, will be authorized.

Will marijuana cigarettes be available for medicinal purposes?

No. Only medicinal products administered orally in the form of capsules, tablets, powders, liquids, solutions or suspensions will be authorized.

Will there be control over the sale of cannabis-based medications?

Yes. Medications will have controls like those currently in place, which may be simply presentation of a prescription in order to purchase, or a more restrictive regime that requires registration and retention of prescriptions.

When taking a medication, will the patient experience the same effects as that of smoking marijuana?

No. The substances extracted from cannabis for the production of medicinal products do not have psychotropic effects.

For which treatments can marijuana-based medications be used?



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The best known use worldwide is for epilepsy. There has been production of medicines or use of the plant for this purpose in other countries, such as Israel, for up to 40 years. Current medications are also effective in the treatment of autism, chronic pain, Parkinson's disease and some types of cancer.

Does the decision of Tuesday, June 11, automatically allow the production of marijuana in the country?

No. After public consultation, Anvisa advisors will evaluate the suggestions and decide whether or not to accept the revisions to the text, and forward for debate at a meeting of the directors, who will then vote on approving the new rules for the sector.