

CANNABIS-BASED DRUGS

Laboratories are beginning to invest in the production of plant-based medications, as well as synthetic and natural cannabidiol, upon approval by Anvisa.

Inaldo Cristoni



Production of cannabis-based medications will most likely see robust growth in the coming years, opening a new field of development in the pharmaceutical industry. The strong growth potential of this market is being explored by the Brazilian company Prati-Donaduzzi and the Canadian company Verdemed.

Prati-Donaduzzi has invested a total of R\$7 million in a suite of active pharmaceutical inputs (APIs) for the production of synthetic cannabidiol. Located in Toledo (PR), its new plant has the capacity to produce 500 grams of the product annually. Half will be used to cover the company's own requirements, and the balance will be set aside for export.

The chemical composition of synthetic cannabidiol is similar to the plant-based version, explains Eder Mafisoni, the company's CEO. "The advantage is that you can control a production process that has 230 distinct stages. Natural cannabidiol is highly vulnerable to environmental conditions."

Five years ago, the laboratory began to develop Myalo, a drug intended for the treatment of refractory epilepsy; this will be the company's first cannabidiol-based product. It expects to submit Myalo to the Brazilian Health Regulatory Agency (Anvisa) for approval toward the end of the year and, after receiving market authorization, it plans to begin commercialization.

In a proposal to develop pharmaceutical products

With an aggressive strategy in Brazil, Verdemed intends to market its medication below the current market price. According to Bacellar, the initial price will be US\$400, but as the volume of sales grows, he expects it to fall to US\$150.

Verdemed will invest US\$10 million in Brazil to buy the Mydstein laboratory, which acts as an importer of medicines, and to establish the Verdemed Care unit, which will be responsible for the e-commerce operations of its phytotherapeutic product line. The company is also negotiating an agreement with two pharmaceutical companies for local production of cannabis-based medications.

Verdemed, currently operating in Brazil, Colombia

from natural cannabidiol, Verdemed submitted a product similar to Sativex (Metavyl), indicated for patients with multiple sclerosis, as well as one similar to Epidiolex, intended to treat refractory epilepsy, for approval by Anvisa. Sativex and Epidiolex have already been approved in the United States. The challenge for Verdemed is to verify that its drug is the bioequivalent of Epidiolex. "What we are asking is that Anvisa grant market authorization based on the existing clinical data. If we have to perform new clinical studies, the launch of the product in Brazil will not be viable," says José Bacellar, president of the company.

and Chile, plans to begin operations in Argentina, Mexico and Peru next year. In Colombia, it has a medical cannabis plantation, at which it produces cannabis oil for export to Europe. By 2022, it expects to invest US\$80 million in clinical trials of medications for anxiety, chronic pain, fibromyalgia and glaucoma.