



6th Edition BRAZIL – CANADA Healthcare Forum

Medical Cannabis Opportunities in Brazil

Cannabis Legal Framework in Brazil

Legal
Authorization
LAW
11.343/2006

*Allows
planting,
cultivation and
harvesting of
medicinal plant
drugs*

“Art. 2º Stay forbidden, throughout the national territory, drugs as well as planting, cultivation, harvesting and exploitation of plants and substrates from which drugs may be extracted or produced, except in the case of legal or regulatory authorization, as well as established in the Vienna Convention on Psychotropic Substances, concerning plants of strictly ritualistic-religious use.

Single paragraph. The Union can authorize planting, cultivation and harvesting of the plants referred to in the main section of this Article, solely for medicinal or scientific purposes, at a predetermined place and within a specified period, subject to supervision, following abovementioned reservations ”.

Regulatory Framework History

1998	2014	2015	2016			2017	2019	2019
National Sanitary Vigilance Agency ANVISA	Federal Council of Medicine CFM	ANVISA		ANVISA		ANVISA	ANVISA	ANVISA
Legal act SVS 344/98	Ordinance 2.113/14	RDC 17/15	RDC 66/16	RDC 128/16	RDC 130/16	RDC 156/17	Public Consultation	RDC 314/19
Classifies the plant Cannabis sativa sp. (List E) and the THC substance (List F2) as outlawed	Allows compassionate use of CBD extracts for treatment of epilepsy in children and young people.	Regulatory Framework for exceptional import by individuals of medicinal products derived from Cannabis	Changed import procedures to also allow THC-based products and medicines	Added six new products to RDC 17/15 list	Allows registration of medicines composed of up to 30 mg / l THC and CBD in Brazil	Updated the list of Common Brazilian Denominations - DCB to include Cannabis Sativa sp. between the list of medicinal plants	Approved, on 6/11, two public consultations on Cannabis cultivation and drug registration	Included in the Ordinance 344/89 exceptional import m.p. and 30 ml CDB and THC

Judicialization of Access

- The Brazilian Ministry of Health spent about R\$ 617,000 in 2018 in cannabis based drugs - more than doubling previous year's spending (R\$ 277,000).
- **In the State of São Paulo**, government expenditure with cannabis based drugs and products increased 18 times (1,750%) in 4 years. It already represents 9.5% of the total amount of drugs that requires an approval through court order. In 2015, the total value of medical cannabis based products imported in Brazil was R\$ 15,200 – between January and June of 2019, Anvisa approved 45 different types of products with a total value of R\$ 4,6 million.
- According to Anvisa, since 2015 there has been an increase in the number of authorized prescribers and patients to import therapeutic products

AUTHORIZED PATIENTS **7.780**

PRESCRIBERS **911**

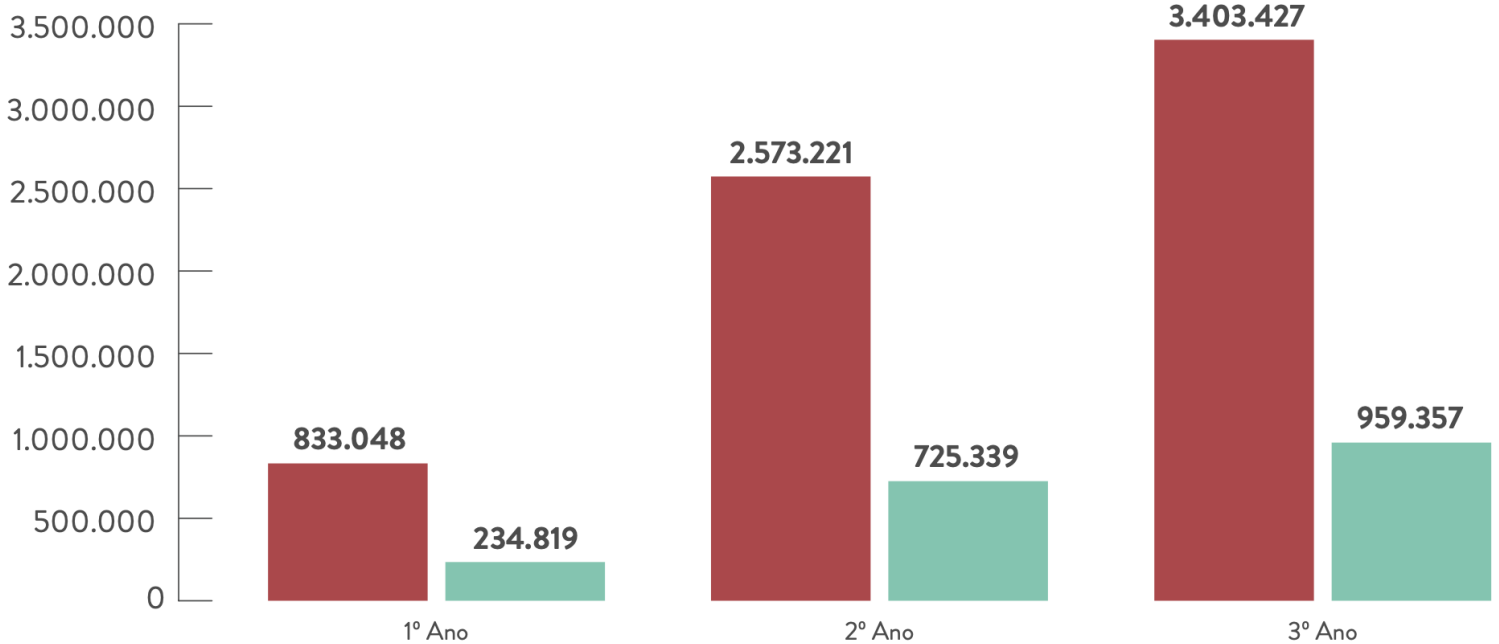
THERAPEUTIC INDICATIONS more than 60 different diseases

The lack of regulation does not allow quality control and safety

The Brazilian Medical Cannabis Market

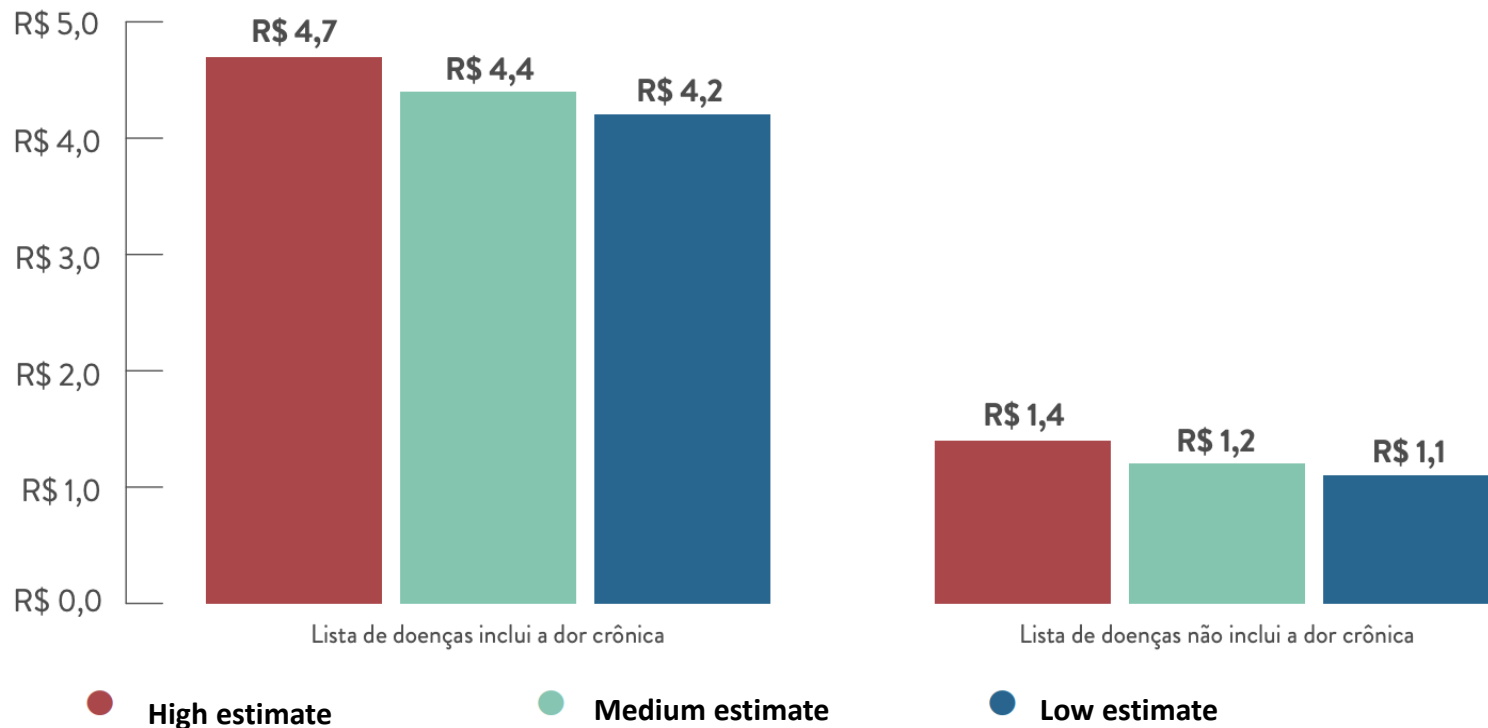
- ✓ In 36 months of legal sales, the number of patients benefiting from cannabis-based drugs will be over 3.4 billion
- ✓ During the first three years of legal sales, the Medical Cannabis Market turnover can reach R\$ 4.7 billion annually ;
- ✓ In all scenarios, cannabis drugs could exceed R\$ 1 billion per year in tax revenue;
- ✓ Brazil could become the main player in Latin America with a potential market of around R\$ 10 billion – and over R\$ 2.5 billion in tax revenue;

Potential number of patients after 3 years



- List of diseases includes chronic pain
- List of diseases does not include chronic pain

Estimated revenue after 3 years



Lessons Learned & Challenges Along the Way

Development of the Medical Cannabis Market

Education and Qualified Information x Stigma

Medical Training

Product Registration – Time and Investment

Pharma Mindset and Company DNA

Relationship with Multiple Stakeholders

Government Agencies – Anvisa

Government Agencies– MS – MAPA (Brazilian Ministry of Agriculture)

Congress – House and Senate

State-Level Government

Universities and Research Centers

Relationship with Patient Associations

Product Access and Quality

Global Outlook: Important Facts

According to Deloitte Management Services, the Canadian market opening for food, beverages, cosmetics and others is estimated to reach \$ 2.7 billion;

Expected changes in the US market such as the approval of the *Banking Act SAFE* and the advancement of the *MORE act*, will allow the cannabis companies to be regulated as well as to open the market for adult consumption beyond the current 34 states where the use of medical cannabis is legal.

Canadian companies are moving toward the US market due to its size and potential;

The drop in share prices motivated by poor delivery of results in recent quarters has led to the outflow of speculative capital. The situation has reversed as soon as demand surpassed offers;

The market potential is on Medicinal Cannabis - data indicates that while only a few countries are legalizing adult consumption, more than 40 countries have some form of medical legalization – resulting in advancements for clinical research and increase in applications analysis.