Brazilian regulatory agency (ANVISA) inaugurates discussion on cannabis for medicinal and scientific purposes

By Anderson Ribeiro

ANVISA's Board of Directors approved today the proposal to open two Public Consultations to regulate:

(i) the cultivation of the cannabis spp. for medical and scientific purposes; and
(ii) a specific procedure for registration and monitoring of medicines based on Cannabis spp., its derivatives, and synthetic analogs.

Next steps
The Directors decided to open the public consultations for 60 days triggered by the publication in the National Official Gazette.

Expected impact
Currently, there is only one imported Cannabis-based medicine registered in Brazil, Mevatyl® (tetrahydrocannabinol + cannabidiol), while major obstacles persist to local R&D, cultivation and manufacturing.

The Brazilian market demand is currently met by imported products and importation of products with cannabinoids is authorized on an individual basis and under prescription and must be renewed every year. In 2018 ANVISA has granted more than 3,000 individual licenses for an array of products without registration.

The future discussion on the use of Cannabis for medical and scientific purposes is a key step to create legal certainty and enable future investment in this segment.

In case you need clarification on the topic, you can reach our team via e-mail: regulatorio@kasznarleonardos.com.