LIFE SCIENCES & HEALTHCARE

CLIENT ALERT

JUNE / 2019

PUBLIC CONSULTATION ON MEDICINAL *CANNABIS*

On June 11, 2019, the National Sanitary Surveillance Agency (Anvisa) approved on an open meeting of the collegiate board, two public consultations aiming at the regulation of the controlled cultivation of *Cannabis sativa* for medicinal and scientific use and the registration of medical products produced with active ingredients of the plant.

One of the proposals for the issuance of a Collegiate Board Resolution ("RDC") deals with the technical and administrative requirements for the cultivation of the plant by legal entities holding a special authorization in indoor strictly supervised areas for medicinal and scientific purposes. The other proposal provides for the procedures for the registration and monitoring of medical products with ingredients of *Cannabis* spp., its derivatives and synthetic analogues.

The rules are rigorous with respect to the chain of production, distribution and consumption of the medication, from the manufacturer, through the transporter and drugstores, all the way to the patient.

The regulatory process on this subject began on 2017 with the set-up of a technical group. Anvisa identified, on the one hand, the difficulty for patients to safely access medical products based on *Cannabis* and its derivatives, and, on the other hand, the high cost of the treatments, with could be reduced with national production.

As of 2015, Anvisa already authorizes the importation of medicines based on cannabidiol and other cannabinoids for personal use, on an exceptional basis, by prescription of a legally qualified professional. In 2015 the number of requests for an special authorization for import was 901, in 2018, it reached the 3.330 mark.

After the publication of the RDC proposals in the Federal Official Gazette, the consultations shall be open to contributions from companies, universities, government and consumer protection bodies, as well as from health professionals and the general population, for a period of 60 days.

Veirano's Life Sciences & Healthcare team is at your attention to provide further information on this matter.

PRACTICE AREA
Life Sciences & Healthcare

COORDINATION
Lior Pinsky
Renata Fialho de Oliveira

For further information, please send a message to news@veirano.com.br

This document was prepared exclusively for informational purposes and does not constitute legal advice or an invitation to an attorney-client relationship. If you have any questions, our lawyers are available for clarification.

It is forbidden to distribute, reproduce or transmit this document, in full or in part, without the prior consent of Veirano Advogados.

© 2019 Veirano Advogados.
All rights reserved.