Brief technical analysis as the regularization of cannabis-based products

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In recent months one of the main agendas involving the Brazilian sanitary regulation was the regulation of cannabis products. After various types of discussions in different sectors of society, from a technical and regulatory point of view, we recently had the publications of Resolutions RDC No. 327/2019 and 335/2020. Substances and drugs subject to special control (narcotics and psychotropic substances) are already subject to sanitary controls, before the creation of ANVISA itself, it is not new that we obtain another substance that must comply with the control and traceability requirements by means of a prescription issued by qualified medical professional, as well as the signing of the Informed Consent Form (TCLE) by the patient or his legal guardian.

After the Second World War, the pharmaceutical chain specialized mainly in active ingredients of synthetic origin, the active ingredients of plant or biological origin, remain a challenge.

Proof of this is that the main world pharmacopoeias present mostly monographs of synthetic substances, recently that investments began to be made in the development of standardization of monographs of biological and herbal medicines. Although many plants have been public knowledge for a long time, many substances of plant origin still need to be standardized.

The production or import of products or drugs based on cannabis goes far beyond ethical and moral discussions, we health professionals must ensure that technical and scientific studies meet regulatory requirements to ensure the safety, efficacy and quality of population health.

Active principles of plant origin may present other secondary substances, so it is important to have specific experience and knowledge in analytical methodologies for plant substances, to even be able to obtain the best suppliers of this raw material or finished product.

Although the Resolution RDC No. 327/2019 brings the new concept of "*cannabis products*", with sanitary authorization for commercialization for 5 years, as long as the company presents all certifications, authorizations and consistent studies, the same cannot be renewed, it should be classified as a medicine.

That is, if the company does not develop a technical and regulatory strategy from the beginning, it may not be able to continue selling the same product in Brazilian territory. And the great challenge is in the construction of the appropriate regulatory strategy, in order to provide that clinical and scientific research studies are in compliance with the requirements for the registration of medicines, as well as with international regulatory and price registration requirements to provide that the company to expand its business in a sustainable and robust way to different countries.

This is yet another example that sanitary regulation, when worked with technical and scientific methodologies, may shed light on the innovation of products and therapies in favor of the progress of the population.