Import authorization simplified for Covid-19-related health products

On March 29th, President Jair Bolsonaro signed into law Bill H.R. #864, of 2020. Effective immediately, Law #14.006, of May 28th, 2020 simplifies the COVID-19 exceptional import regime for health products without register in the Brazilian Food and Drug Agency (ANVISA).

The new Law revokes the need for a normative act issued by the Ministry of Health to authorize the imports. Now, the decision on the authorization grant is restricted to ANVISA's assessment.

The exceptional regime is only applicable to health products used to face the Covid-19 pandemic outbreak. The Law also requires that these products must be registered by at least one of four specific foreign agencies for the special authorization to be granted by ANVISA.

According to the text, the authorization may be granted for drugs, equipment, or material used to face the Covid-19 outbreak that have already been registered by at least one of the following foreign agencies:

i. Food and Drug Administration (FDA);

ii. European Medicines Agency (EMA);

iii. Pharmaceutical and Medicines Device Agency (PMDA), and;

iv. National Medical Products Administration (NMPA).

Also, the text determines that, when prescribing or administering such products to any person, physicians must inform the patient about the lack of marketing approval by ANVISA and that a foreign marketing approval supports their use in Brazil.

President Bolsonaro vetoed part of the bill's text that granted a "tacit authorization" in case ANVISA did not examine these requests within 72 hours after their filing. The article, included as an amendment proposed by the Senate, was vetoed because the Executive Branch considered that it violated an exclusive competence of the President.

The special regime will only be in force during the public health emergency declared by the Ministry of Health due to the COVID-19 pandemic, as provided in Law #13,979/2020.