McConnell Valdés LLC

PR Department of Health Grants Extension to Certain Non-Resident Distributors to Comply with Special Authorization Requirement

ATTORNEYS

- Arturo J. García-Solá
- Lizzie M. Portela-Fernández
- Samuel T. Céspedes Jr.
- Roberto Prats-Palerm
- Marcos Rodríguez-Ema
- Adrián P. Goyco-Vera
- Luis Augusto Martínez-Román

PRACTICE AREAS

- Health Care

An McV Health Care Alert

August 29, 2024

As previously notified in our July 14, 2022 McV Health Care Alert, U.S. distributors that desire to engage in the wholesale distribution of prescription and non-prescription drugs, homeopathic products, natural products, nutritional supplements and/or medical devices in Puerto Rico need to apply for a Special Authorization (the "Special Authorization") issued by the Puerto Rico Department of Health (PRDOH). This requirement became effective on July 1, 2022.

On August 19, 2024, the Puerto Rico Department of Health (the "PRDOH") issued a letter ("Letter") informing that many non-resident distributors have failed to obtain the Special Authorization, and this situation has affected the registration of drug products that are intended to be distributed in Puerto Rico.

The PRDOH is granting an additional ninety (90) days from the date of issuance of the Letter to allow non-resident distributors of oncology drugs, vaccines and/or antibiotics to comply with the Special Authorization requirements. During this time, the PRDOH will register these types of drug products, regardless of whether the non-resident distributor has obtained the Special Authorization. Failure to comply with the Special Authorization requirement after the ninety (90) day period may result in the cancellation of the registration of the drug products supplied by the non-resident distributor.

The content of this McV Alert has been prepared for information purposes only. It is not intended as, and does not constitute, either legal advice or solicitation of any prospective client. An attorney-client relationship with McConnell Valdés LLC cannot be formed by reading or responding to this McV Alert. Such a relationship may be formed only by express agreement with McConnell Valdés LLC.