

## Non-Resident U.S. Distributors Now Required to Obtain Special Authorization to Distribute Medications and Medical Devices in Puerto Rico

### ATTORNEYS

- Lizzie M. Portela-Fernández
- Samuel T. Céspedes Jr.
- Francisco J. Pavía
- Adrián P. Goyco-Vera

### PRACTICE AREAS

- Health Care

### An McV Health Care Alert

July 14, 2022

On June 29, 2022, the Puerto Rico Department of Health informed that, effective July 1, 2022, 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 (“Non-Resident Distributors”) will need to apply for a Special Authorization issued by the Office of the Assistant Secretary for the Regulation and Accreditation of Healthcare Facilities (SARAFS).

To obtain the Special Authorization, the Non-Resident Distributors will need to file a self-certification form with the Puerto Rico Department of Health, a criminal background report, a drug registration certificate of compliance and a bond certificate, among other documents. The Special Authorization for Non-Resident Distributors is renewable every two (2) years.

The Drugs and Pharmacy Division of SARAFS reserves the right to inspect Non-Resident Distributors and any costs of travel, lodging and transportation will be borne by the Non-Resident Distributors.

Pursuant to the Department of Health, this new requirement is adopted in accordance with the provisions of the Puerto Rico Pharmacy Act, Act No. 247-2004, as amended, and related regulations. Failure to comply with said Act and its regulations may result in sanctions by the SARAFS, including the imposition of fines and forfeiture of the required bond.

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.