

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

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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.

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