

Special Authorization Requirement for Virtual Manufacturers and Virtual Distributors

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The Puerto Rico Department of Health (the “Department of Health”) issued Administrative Order No. 564 (the “Administrative Order”) to require virtual manufacturers and virtual distributors of certain pharmaceutical products to obtain a special authorization for conducting business in Puerto Rico. The Department of Health began receiving special authorization applications on March 15, 2023.

The Administrative Order defines *virtual manufacturers* as resident and non-resident entities that sell their own drugs, homeopathic products, veterinary drugs, natural products, supplements, and/or medical devices (collectively, the “Pharmaceutical Products”), but subcontract the manufacturing activities of such Pharmaceutical Products to a third party. *Virtual manufacturers* never come into contact with such Pharmaceutical Products in Puerto Rico. *Virtual Distributors* are entities engaged in the purchase and sale of Pharmaceutical Products without coming into physical contact with them. These *virtual distributors* do not manufacture, store, prescribe, or promote Pharmaceutical Products, but are experts in third party logistics (3PL).

The special authorization is valid for one (1) year after its issuance. To obtain the special authorization, the *virtual manufacturers* and *virtual distributors* must file an application with the Department of Health.

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