

Dear Client,

Last year SARAFS, the local government office responsible for overseeing licensing of healthcare products and facilities, issued a notice indicating that non –resident distributors should request a special permit in order to sell their products in Puerto Rico.

We have been in communication with SARAFS since then, respectfully challenging the broad nature of the notice and the resulting over regulation of companies that delegate distribution on dully licensed local distributors and representative agents. We went as far as to retain the services of McConell Valdes LLC law firm to look into the matter with us and meet together with SARAFS. Unfortunately, we are yet to receive formal response to our queries and/ or recommendations. They agree with us in that the manufacturer’s and distributor’s information is being collected during product registration process but the special permit platform does not communicate with the product platform, therefore the need for an additional transaction.

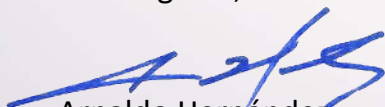
In our last meeting we discussed about the possibility of focusing the special permit on the Marketing Authorization Holder instead of each distribution site. The term they use for this is “virtual manufacturer” but at this time it is only implemented for local entities. SARAFS recently relocated and this has resulted in additional service delays.

It is my opinion that it would take a concerted industry lobbying effort and /or a change in SARAFS leadership in order to achieve material change on this new requirement. Since the financial impact of the special non-resident permit is not significant for large pharmaceutical companies, this effort is not likely to happen.

We will not give up on working with SARAFS and our clients in order to reach outcomes favorable for all in the industry. However, for now it is our recommendation to revisit the requirements for the special permit and start working on developing a dossier, to be completed and filed once we receive final comments and /or deadline from SARAFS. Please see Annex 1 for the updated requirements.

Feel free to contact us if any questions arise.

Kind regards,



Arnaldo Hernández
President
Rebexa Group Inc.