CONCEPT OF MANUFACTURER IN REGISTRO AND CADASTRO REGISTRATION PROCESSES OF IMPORTED HEALTHCARE PRODUCTS

Considering the need to unify the understanding related to the concept of manufacturer in registration processes of imported healthcare products (medical devices and in-vitro diagnostic products), the National Health Surveillance Agency, through the General Management of Technology of Healthcare Products - GGTPS and the General Management of Ports, Airports, Borders and Customs – GGPAF, hereby presents the following clarifications:

For registration purposes, a manufacturer of imported healthcare products is considered to be the company responsible for the product overseas, formally recognized by the health surveillance authority of their country of origin, even when part or all of the manufacturing process is carried out by a third party. Internationally, this is the concept of legal manufacturer.

Seeking to solve doubts as to the real manufacturer of products upon importation and its inspection, GGTPS adopted the terminology "Manufactured by Company X for Company Y" as a way to identify the manufacturer responsible for the product and its third party. However, in view of some changes in international regulations, the labeling of these products began to display the names of several companies related to the location(s) of distribution, shipping, manufacture and the company’s legal representative in the United States or in the European Community. This situation greatly increased the number of inquiries made to GGTPS, which is delaying customs clearance and increasing the demand of change applications.

Having said that, GGTPS will adopt the following procedures for registration processes:

1) For registrations at GGTPS, the information in the field to identify the manufacturer must indicate solely the name of the only company responsible for the product overseas, formally recognized by the health surveillance authority of their country of origin.

Subcontractors must not be indicated in this field.

2) The applications that have already been registered at GGTPS will be slowly changed through the analysis of any application submitted by the company (alteration or revalidation requests). The changes in question refer to the exclusion of subcontractors from the field intended for identifying manufacturers, leaving solely the name of the manufacturer responsible for the product. We would also like to point out that there is no need to submit an application to change manufacturer if the process is already in the situation "Manufactured by Company X for Company Y".

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