Circular Informativa

N.º 143/CD/100.20.200

Data: 30/07/2015

Assunto: **Submissão de traduções**

Para: Divulgação geral

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In order to simplify the evaluation process of the translation to Portuguese of the summary of product characteristics (SPC), package leaflet (PL) and labelling, submitted during the market authorization application (MA), variations and renewal by the procedures of mutual recognition and decentralized, Infarmed adopted the following measures:

1) Evaluation of the translations based on risk criteria

a. The Applicants must submit, together with the Portuguese versions of the SPC, FI and labelling, a "Declaration of compliance of national translations of the product information", to demonstrate the accuracy of the translations submitted;

b. Infarmed adopts different methodologies for the revision, according to the associated risk identified by risk criteria;

c. The "Declaration of compliance of national translations of the product information" is submitted only once, together with the texts, and should not be submitted response to requests during the evaluation.

2) Conclusion of MA applications, changes and renovations without the approval of the portuguese version of the information

a. Applicable in cases where the applicant does not intend to start immediately, the marketing of the product;

b. For this, the applicants must submit a "Declaration of non-commercialization of the medicinal product";

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c. The approval of the Portuguese information must be requested 4 months before the MAH decides to market the medicinal product. This information must identify the regulatory procedures, already approved by the reference member state (RMS), the last English version of the product information and its translation into Portuguese, as well as the Declaration of compliance of national translations.

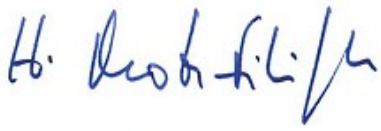
3) MA applications, variations and renewals waiting Infarmed's decision

The applicants must submit the "Declaration of non-commercialization of the medicinal product" or "Declaration of compliance of national translations of the product information" regarding applications that are currently under evaluation.

These statements can be submitted by email, along with the latest version of the "Declaration form for the use of e-mail communications with Infarmed", used in SMUH-AIM and SMUH-ALTER, if it hasn't already been sent.

These measures are based on other Member States experience and supported by the European associations (EFPIA and EGA). APIFARMA and APOGEN have also been consulted.

The Executive Board



Helder Mota Filipe
Vice-Presidente
do Conselho Diretivo

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