

Circular Informativa

N.º 048/CD/100.20.200

Data: 19/07/2024

Assunto: **Availability on Infomed of SmPC and PIL after the conclusion of clinical variations and renewals in which Portugal acts as an Concerned Member State (PT-CMS) – MRP/DCP marketing authorisations and national marketing authorisations in MRP worksharings**

Para: Divulgação geral

Contacto: Centro de Informação do Medicamento e dos Produtos de Saúde (CIMI); Tel. 21 798 7373;
E-mail: cimi@infarmed.pt; Linha do Medicamento: 800 222 444

With the aim to clarify the procedure for publishing in Infomed the summaries of product characteristics (SmPC) and package leaflets (PL) in cases of category C variations or renewals in which Portugal acts as the concerned Member State (CMS) previously disclosed in the Circular Informativa [191/CD/100.20.200](#) of 16/12/2020, the following is hereby informed:

- The implementation of the variations approved by the mutual recognition procedure in which Portugal is a CMS does not require that the variation is with the status “finalized” in Smuhalter. Implementation can be carried out from the notification of approval by the reference Member State (RMS). The notifications regarding the conclusion of a variation through this procedure are sent only by the RMS, no communication is sent by Infarmed
- The simplified procedure for making the texts of SmPC and PL available in Infomed is applicable also to national marketing authorisations included in worksharings with Portugal as a CMS
- The texts of SmPC and PL of medicines with changes/renewals already completed but not yet published must also be sent for publication

As detailed in Circular Informativa [191/CD/100.20.200](#), the procedure consists of sending the texts of SmPC and PL in Portuguese to the email address infomed_cms.post@infarmed.pt for all category

C variations, regardless of whether they are type IA, type IB or type II, and renewals in which the SmPC and/or PL has been updated.

The email templates for sending the texts and the applicable documentation are described in detail in the above mentioned Circular Informativa.

The [frequently asked questions](#) document on variations, available on Infarmed's website, will be updated with this information.

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