Circular Informativa

N.º 010/CD/100.20.200

Data: 22/01/2021

Assunto: **Publication of SmPCs and PLs in Infomed from clinical variations and renewals with Portugal as Concerned Member State (PT-CMS) – Correction of Circular Informativa No. 191/CD/100.20.200 of 16/12/2020**

Para: Divulgação geral

Contacto: Centro de Informação do Medicamento e dos Produtos de Saúde (CIMI); Tel. 21 798 7373; Fax: 21 111 7552; E-mail: cimi@infarmed.pt; Linha do Medicamento: 800 222 444

In order to publish in Infomed the national versions (translations) of the summary of product characteristics (SmPC) and package leaflets (PL) approved in clinical variations and renewals where PT is a CMS, either regarding medicinal products with finished procedures without the duly publication of the SmPC/PL or after the conclusion of new variations and renewals, Infarmed adopted the following measures:

1) Use of the email box infomed_cms.post@infarmed.pt

Applicants shall submit the following documentation to the referred email box for all category C variations, regardless of whether they are type IA, type IB or type II and renewals where a new SmPC/PL are approved, either for medicinal products with completed procedures without duly publication of the SmPC/PL or after the conclusion of new variations and renewals:

- National consolidated versions (Portuguese translation) of the SmPC, PL and labelling for clinical variations/renewal concluded by Reference Member State (RMS) (please use the email template provided in Annex 1);

- Declaration of compliance of national translations of the product information, according to Circular Informativa Nº 143/CD/100.20.200 de 30/07/2015;

- List of variations/renewal corresponding to the submitted consolidated SmPC/PL/labelling national version in tabular format according to the template provided in Annex 1.

- Declaration of non-commercialisation of the medicinal product, according to Circular Informativa Nº 143/CD/100.20.200 de 30/07/2015, in cases where marketing authorisation

INFARMED - Autoridade Nacional do Medicamento e Produtos de Saúde, I.P.
Parque de Saúde de Lisboa - Av. do Brasil, 53
1749-004 Lisboa
Tel.: +351 217 987 100 **Fax**: +351 217 987 316 **Website:** www.infarmed.pt **E-mail**: infarmed@infarmed.pt

holders do not wish to submit national translations due to non-commercialisation of the medicinal product. This statement should be submitted together with the listing of the corresponding variations/renewal using the e-mail template in Annex 2.

2) **Update of the document regarding frequent questions - variations available on the Infarmed´s website** with clarification of questions received by Infarmed about the publication of texts in Infomed and approval dates.

This new procedure applies from 1 January 2021.

Executive Board

António Manuel Núncio Faria Vaz

Assinado de forma digital por António Manuel Núncio Faria Vaz
Dados: 2021.01.22 16:34:44 Z

INFARMED - Autoridade Nacional do Medicamento e Produtos de Saúde, I.P.
Parque de Saúde de Lisboa - Av. do Brasil, 53
1749-004 Lisboa
Tel.: +351 217 987 100 **Fax**: +351 217 987 316 **Website:** www.infarmed.pt **E-mail**: infarmed@infarmed.pt

Annex 1 – Email template for the submission of consolidated versions of SmPC/PL/labelling and listing of corresponding variations/renewal

From:

To: infomed_cms.post@infarmed.pt

Subject: **«Marketing Authorisation Procedure Number (e.g. PT/H/9653/001)»** - **«Name of the medicinal product»** - Publication of product information - C.I. 010/CD/100.20.200

In accordance with Circular Informativa No. 010/CD/100.20.200 de 22/01/2021, regarding the publication of product information from category C variations/renewal with PT as CMS, the following is provided:

- National consolidated versions of the «SmPC», «PL» «and labelling», which concern the following variations/renewal

Variation/renewal procedure number[1)]	Date of submission in SMUH-Alter	Medicinal product name	Strength	Pharmaceutical form

[1)] In case of grouped or work-sharing applications, please state only the variation procedure number and not the MRP variation number

- Declaration of compliance of national translations of the product information;

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Parque de Saúde de Lisboa - Av. do Brasil, 53
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Tel.: +351 217 987 100 **Fax**: +351 217 987 316 **Website:** www.infarmed.pt **E-mail**: infarmed@infarmed.pt

Annex 2 – Email template for the submission of Declaration of non-commercialisation of the medicinal product

From:

To: infomed_cms.post@infarmed.pt

Subject: **«Marketing Authorisation Procedure Number (e.g. PT/H/9653/001)»** - **«Name of the medicinal product»** - Publication of product information - C.I. 010/CD/100.20.200

In accordance with Circular Informativa No. 010/CD/100.20.200 de 22/01/2021, regarding the publication of product information from category C variations/renewal with PT as CMS, we hereby submit a **Declaration of non-commercialisation of the medicinal product** and request not to submit the national translations of the SmPC/PL/labelling approved in the following procedures:

Variation/renewal procedure number[1)]	Date of submission in SMUH-Alter	Medicinal product name	Strength	Pharmaceutical form

[1)] In case of grouped or work-sharing applications, please state only the variation procedure number and not the MRP variation number

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