

## Circular Informativa

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N.º 188/CD/100.20.200

Data: 30/12/2016

Assunto: **Electronic submission of renewals, transfer of MAH and changes to the labelling or the package leaflet not connected with the SmPC**

Para: Titulares de AIM, Apifarma, Apogen, Aprefar, Fecofar, Groquifar e Norquifar

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The SIMPLEX 2016 program aims to meet the needs of citizens and companies in their interaction with Public Institutions, making it simpler and more effective.

Within the scope of this program and in order to fully dematerialize its procedures, Infarmed has revised the submission of renewals, Marketing Authorisation Holders (MAH) transfers and update of labelling and/or patient Information leaflet (PIL) not connected with the summary of product characteristics (SmPC).

Therefore, please be informed that:

1. Applications for renewals, MAH transfers and update of labelling and/or PIL not related with the SPC must be submitted exclusively online, using the electronic platform [Medicinal Product for Human Use Management System \(SMUH-ALTER\)](#) available at Infarmed's website.
2. Regardless of the type of procedure, the submission of these applications will be performed **exclusively and mandatorily** through the electronic platform from **February 1<sup>st</sup> 2017**.
3. For a transition period starting January 3<sup>rd</sup> 2017, both submission according to the previous procedure and the new electronic only submission are acceptable
4. Additionally, the list of fees applicable to these type of requests is available at the online submission platform (SMUH-ALTER), in accordance with *Circular Informativa N.º 124/CD/100.20.200*, of 07/07/2015.

The Instructions to Applicants for submitting variations, renewals and MAH transfers were revised and are available at Infarmed's website.

The Executive Board