Circular Informativa

N.º 187/CD/100.20.200

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Assunto: **Submission of new Marketing Authorisation Applications**

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 the Public Institutions, making it simpler and more effective.

Within the scope of this program and in order to fully dematerialize its procedure, Infarmed has revised the submission of new Marketing Authorisation Applications by national and mutual recognition/decentralised procedures.

Therefore, please be informed that:

1. After the pre-submission of the marketing authorisation applications to Infarmed through the SMUH-AIM platform, the submission of these applications must be made exclusively via CESP (Common European Submission Portal);
2. Documentation in paper or CD should not be sent to Infarmed;
3. Submission of additional documentation during the procedure's evaluation must be made exclusively electronically via CESP (Common European Submission Portal) or by email.
4. Regardless of the type of the authorisation procedure, the submission of these applications will be performed **exclusively and mandatorily** via CESP from **February 1st 2017.**
5. For a transition period starting January 3rd 2017, both submission according to the previous procedure and the new electronic only submission are acceptable

The Instructions to Applicants for submitting the new Marketing Authorisation Applications were revised and are available at Infarmed's website.

The Executive Board

Helder Dias Mota Filipe

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