Circular Informativa

N.º 003/CD/100.20.200

Data: 03/01/2019

Assunto: **Falsified Medicines Directive – packaging adaptation**

Para: Titulares de AIM

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

The Directive 2011/62/EU of the European Parliament and of the Council ("Falsified Medicines" Directive), introduced the inclusion of the unique identifier in the packaging to allow an adequate detection of falsified medicines and an individual identification of packages.

Marketing authorisation holders may submit a Notification, pursuant to article 61(3) of Directive 2001/83/EC, providing an updated version of the QRD template, that confirms the implementation of the safety features on the packaging via SMUH-Alter portal.

To expedite this assessment, we advise that these requests are made with this sole purpose, and that the cover letter includes reference that the changes apply to sections 17 and 18 of the template and no other changes to the content of the template have been made.

The Executive Board

Maria Sofia Rodrigues Pintado de Oliveira Martins

Assinado de forma digital por Maria Sofia Rodrigues Pintado de Oliveira Martins
Dados: 2019.01.04 19:00:23 Z

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