Information Circular

N.º 051/CD/100.20.200

Date: 11/02/2020

Subject: **Evaluation of the presence of nitrosamine in medicinal products - form**

To: MA holders

Contact: 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

As described in Circular Informativa n.º 145/CD/100.20.200, marketing authorisations holders (MAH), as a precautionary measure, have to review medicinal products with chemically synthesized active substances, in order to verify the presence of nitrosamines and test all medicinal products with potential risk, reporting, in both cases, the results to the National Competent Authorities.

In order to facilitate the evaluation of the presence of nitrosamines in all medicinal products, there is an electronic form available via SMUH-ALTER. To submit the results of the analysis and nitrosamine risk, MAH must access SMUH-ALTER and select "Nitrosamine Risk Assessment".

For further instructions, please consult Instructions to Applicants available at INFARMED´s website.

The Executive Board

António Manuel Núncio Faria Vaz

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Dados: 2020.02.11 16:27:29 Z

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M-ATEND-00807