Circular Informativa

N.º 145/CD/8.1.6

Data: 25/06/2013

Assunto: **Contact person for pharmacovigilance issues at national level**

Para: Marketing authorisation holders

Contacto: Centro de Informação do Medicamento e dos Produtos de Saúde (CIMI); Tel. 21 798 7373; Fax: 21 798 7107; E-mail: cimi@infarmed.pt; Linha do Medicamento: 800 222 444

With the transposition of Directive 2010/84/EU of the European Parliament and of the Council of 15 December 2010 into the national law (Decreto-Lei n.º 20/2013 of 14 February, amending Decreto-Lei n.º 176/2006 of 30 August) it is required to appoint a contact person for pharmacovigilance issues at national level, who reports to the qualified person for pharmacovigilance.

The contact person for pharmacovigilance issues at national level should meet the following conditions:

- Be appointed by the marketing authorisation holder (MAH);
- Located in Portugal;
- Perform its pharmacovigilance functions in a permanent and continuous way;
- Have appropriate training and experience in pharmacovigilance, knowledge of the Pharmacovigilance System in place and be fluent in Portuguese language.

The qualified person for pharmacovigilance is responsible for the appropriate training and experience of the contact person and should declare it by issuing an appropriate statement.

To appoint the contact person for pharmacovigilance issues at national level, the MAH for medicinal products for human use and traditional herbal medicinal products should complete the Excel file that will be sent to each MAH by the email dam@infarmed.pt.

The file should be sent along with the respective(s) statement(s) of the qualified person for pharmacovigilance within 90 consecutive days to the email address (dam@infarmed.pt).

The contents of the file will be loaded directly into the Infarmed's database. Therefore, the information related to qualified person for pharmacovigilance and the contact person should be completed for each medicinal product, even in case of repeated information.

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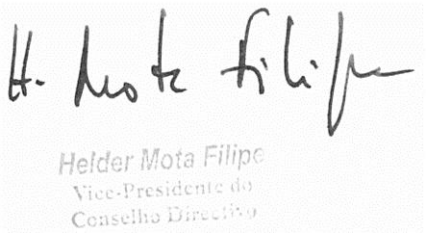
In order to allow Infarmed to send the file to the appropriate contact, MAH should inform the email address to dam@infarmed.pt until July 11th.

These provisions apply to all authorized medicinal products regardless of the evaluation procedure.

The Executive Board



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