NOTICE ON IMPLEMENTATION OF THE PAEDIATRIC REGULATION

Submission of information on existing paediatric studies and paediatric use in accordance with Regulation 1901/2006, from 12 December 2006 (paediatric regulation)

Content:

Introduction

The Paediatric Regulation came into force in the EU on 26 January 2007, and is directly applicable in Member States. The objectives of this Regulation are to facilitate the development and increase accessibility of medicines for children, to ensure high quality research and appropriate authorization of these medicines, and improve the information on their use.

The Regulation contains a number of provisions that must be implemented by Marketing Authorization holders (MAH), National Competent Authorities of each Member State (NCAs) and the European Medicines Agency (EMEA) between July 2007 and January 2010.

The present Notice contains information on the submission by MA holders of line listings of paediatric studies required to comply with the provisions from Articles 32, 42, 45(1) and 46 of the Regulation**.**

The objectives for collecting this information are:

- To help the definition of priorities in the assessment of existing studies, as well as new ones, that need to be submitted under the provisions of Articles

45(1) and 46. These studies will be assessed in a work-sharing system by NCAs. As a result, product information will be updated where appropriate.

- To identify medicinal products that will be eligible for the paediatric symbol, , in accordance with the provisions of Article 32 of the Regulation

- To obtain information on the current uses of medicinal products in the paediatric population. This information shall be gathered by the Member States and communicated to the EMEA by the 26 January 2009, according to the provisions of Article 42.

Procedure

The procedure to be followed is the one agreed by the Co-ordination Group for Mutual Recognition and Decentralized Procedures Human (CMDh), and that is published on the Heads of Agencies (HMAS) website, at http://www.hma.eu/216.html.

The relevant documents published are:

- Procedural guidance
- Addcitional Questions and Answers <> EU questions and answers
- Templates to be used.

The MA Holder must use the templates agreed by the CMD(h) for all the European Union. Information must be submitted to INFARMED I.P. for all the medicinal products approved in Portugal until the **26 January 2008**, with a copy to the EMEA.

Templates to be used

The following templates have been agreed in order to standardize the submission of information in all Member States:

- A line-listing of **all** the medicinal products with marketing authorization in Portugal, indicating whether or not paediatric studies exist.**.** In case of existence of these studies, if they have already been submitted to INFARMED I.P this information should be clearly stated in the relevant column. At this stage there is no need to submit any further information or study details.

  The studies not yet submitted will be sent to the *Rapporteur* at a latter stage, in the framework of the European work sharing system, which will be afterwards put in place

- The Declaration (Annex I) mentioned in the CMD(h) *procedural guidance* must be filled in. This Declaration confirms that all medicinal products are included in the above mentioned line-listing, independently of having or not approved paediatric indications.

- A list (Annex II) of medicinal products having approved paediatric indications. The relevant text from sections 4.1 and 4.2 of the SPC has to be completed. For medicinal products authorised by a purely national procedure, this text will be in Portuguese. For medicinal products approved through a European procedure, the text will be in English. This Annex Iii list may be submitted at a different time from the line-listing and Annex I. The deadline for Annex II submission to INFARMED I.P.is the **26 of April 2008**.

- It is recommended that simultaneously with the submission of this requested information, the MAHs submit a short critical expert overview, clarifying the context of the study and identifying potential regulatory actions, such as variations to the product information. The intention is that this overview can be a tool to facilitate the assessment during the *work sharing* phase.

Submission to INFARMED I.P.

Submission will be only in electronic format. To that end, INFARMED I.P will make available in its website, a specific electronic tool

This tool will be available during the beginning of January 2008. To have access to it, the password will be the same as for on-line submission of variations and marketing authorisation applications.

The MAHs that do not yet have the above mentioned password, must ask for one to the following email address: paediatric.studies@infarmed.pt

Instructions on the use of this electronic tool will be made available in due time.
Until then, the MAHs should collect and analyse the information on their medicinal products, in order to start the submission as soon as the electronic tool is available.

Contact

For further informations on this matter, please send an email to paediatric.studies@infarmed.pt