Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human

European Medicines Agency

PROCEDURAL GUIDANCE CONCERNING SUBMISSION OF INFORMATION ABOUT MEDICINAL PRODUCTS AS REQUESTED BY THE PAEDIATRIC REGULATION[1]

September 2007

Introduction

This document was produced by the CMD(h) and EMEA in order to facilitate the submission of information about medicinal products as requested by the Paediatric Regulation in a harmonised and practical way.

Prerequisite: extracts from European legislation and Commission Communication

Submission of paediatric studies concerning authorised medicinal products according to Art. 45 and 46 of the Paediatric Regulation:

Article 45 of Reg. 1901/2006

1. By 26 January 2008, any paediatric studies already completed, by the date of entry into force, in respect of products authorised in the Community shall be submitted by the marketing authorisation holder for assessment to the competent authority.
The competent authority may update the summary of product characteristics and package leaflet, and may vary the marketing authorisation accordingly. Competent authorities shall exchange information regarding the studies submitted and, as appropriate, their implications for any marketing authorisations concerned.
The Agency shall coordinate the exchange of information.
2. …..

Article 46 of Reg. 1901/2006

1. Any other marketing authorisation holder-sponsored studies which involve the use in the paediatric population of a medicinal product covered by a marketing authorisation, whether or not they are conducted in compliance with an agreed paediatric investigation plan, shall be submitted to the competent authority within six months of completion of the studies concerned.
2. Paragraph 1 shall apply independent of whether or not the marketing authorisation holder intends to apply for a marketing authorisation of a paediatric indication.
3. The competent authority may update the summary of product characteristics and package leaflet, and may vary the marketing authorisation accordingly.
4. Competent authorities shall exchange information regarding the studies submitted and, as appropriate, their implications for any marketing authorisations concerned.
5. The Agency shall coordinate the exchange of information.

[1] Regulation (EC) No 1901/2006 as amended

Identification of all authorised medicinal products with paediatric use:

Symbol – Identification

Article 32 of Reg. 1901/2006
1. Where a medicinal product is granted a marketing authorisation for a paediatric indication, the label shall display the symbol agreed in accordance with paragraph 2. The package leaflet shall contain an explanation of the meaning of the symbol.
2. By 26 January 2008, the Commission shall select a symbol following a recommendation of the Paediatric Committee. The Commission shall make the symbol public.
3. The provisions of this Article shall also apply to medicinal products authorised before the entry into force of this Regulation, and to medicinal products authorised after the entry into force of this Regulation but before the symbol has been made public, if they are authorised for paediatric indications. In this case, the symbol and the explanation referred to in paragraph 1 shall be included in the labelling and package leaflet respectively of the medicinal products concerned not later than two years after the symbol has been made public.

Survey

Article 42 of Reg. 1901/2006
Member States shall collect available data on all existing uses of medicinal products in the paediatric population and shall communicate these data to the Agency by 26 January 2009.
The Paediatric Committee shall provide guidance on the content and the format of the data to be collected by 26 October 2007.

Outline of the Procedure

Each marketing authorisation holder (MAH) has to fill in the template for all their approved products (including purely national, MRP and DCP and centrally authorised products) subdivided for each member state in English language. This obligation applies to all authorised medicinal products.
The line listing with the Annex I and the Annex II, if applicable has to be sent to each competent authority where the product is authorised (not the Member State where studies were performed) in electronic format only. Therefore the competent authorities will dedicate a mailbox or e-mail address for this purpose. A list of these addresses for each competent authority will be published on the CMD-h website.

In addition, for nationally authorised medicinal products (including MRP and DCP), MAHs should send a copy of all the templates to EMEA to the following e-mail address <paedstudies@emea.europa.eu>.
It is recommended that MAHs send to EMEA also an overview of their products and information about the paediatric studies not yet submitted, in addition to the information in the templates. This will facilitate the EU worksharing procedure and the appointment of Rapporteurs.

For filling in the line listing, different scenarios are possible, depending on whether the paediatric data have been already submitted or will be submitted.

In case the **medicinal product** is authorised **for paediatric use** the adequate information has to be stated in the line listing and the relevant wording as stated in the SmPC 4.1 and/or 4.2 has to be given in Annex II in the relevant national language (for nationally authorised medicinal products) or in English for medicinal products authorised via MRP/DCP or centralised procedure.

It has to be further indicated whether:

- All the paediatric studies already completed by 26 January 2007 have been submitted to the Competent Authority, i.e. NCA or the EMEA, irrespective of whether paediatric use was authorised. There is no need to resubmit these data again to the Competent Authority, but a declaration has to be signed by the MAH (Annex I) and sent to theCompetent Authority .

- For nationally authorised medicinal products (including MRP and DCP), in case of paediatric studies completed by 26 January 2007 but not yet submitted to the NCA irrespective of whether paediatric use was authorised – further information has to be given in the line listing by 26 January 2008. The studies will have to be forwarded to the Rapporteur, once appointed, according to priorities set up within the Worksharing exercise in the next 6 months. Information about the Rapporteur will be published on the CMD-h website. The studies have to be assessed by the member states. This will be done within the Paediatric worksharing project, coordinated by the EMEA/CMD-h.

- For centrally authorised medicinal products, in case of paediatric studies completed by 26 January 2007 but not yet submitted to the EMEA irrespective of whether paediatric use was authorised, the paediatric studies together with the line listings will have to be submitted to the EMEA by 26 January 2008.

In order to show how to fill in the relevant information in the line listing, an example of a table (line listing) is annexed which shows different examples.

For further information visit the Q&A document at the HMA-website http://www.hma.eu/99.html