

Date: 18 Dec 2007

Pljujska cesta 21  
SI - 1000 Ljubljana  
t + 386 (0)8 2000 500  
f + 386 (0)8 2000 510  
www.jazmp.si**TO MARKETING AUTHORISATION HOLDERS****Reporting of paediatric data for already approved medicinal products**

The main objective of the Regulation of the European Parliament and of the Council on Medicinal Products for Paediatric Use (EC) No 1901/2006 and (EC) No 1902/2006) is to improve children's health by better regulation of medicines intended for paediatric use.

As a first step to achieving this goal an agreement has been made between EMEA and CMD (h) regarding reporting of paediatric data for already approved medicinal products. Marketing authorisation holders must submit the data according to the guidance document: 'Procedural guidance concerning submission of information about medicinal products as requested by the paediatric regulation'.

The following templates shall be used:

- Submission of Information on Paediatric Studies from MAH to NCAs - line listing;
- Annex I: MAH Declaration (signed declaration should be sent in electronic version only as PDF document);
- Annex II: Listing of Products already authorised for Paediatric use.

Data should be sent before 26 January 2008 (deadline for submission of Annex II is extended to 26 April, 2008) in electronic format only to the e-mail addresses:

**[paedstudies@jazmp.si](mailto:paedstudies@jazmp.si)** with a copy to **[paedstudies@emea.europa.eu](mailto:paedstudies@emea.europa.eu)**

Further information can be found on the web sites and in the following document: 'Q&A on the submission of Paediatric studies'.

**EMEA:** <http://www.emea.europa.eu/htms/human/paediatrics/introduction.htm>

**EU Commission:** <http://ec.europa.eu/enterprise/pharmaceuticals/paediatrics/index.htm>

**Heads of Medicines Agencies:** <http://hma.eu/213.html>

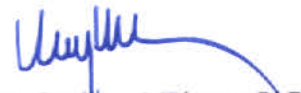
For any further information please contact the following e-mail address:

**[paedstudies@jazmp.si](mailto:paedstudies@jazmp.si)**

Kind regards,



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Martina Cvelbar, MPharm, PhD  
director