English version

The Paediatric Regulation foresees also national actions for the already authorised medicinal products, as detailed in art. 45 and 46 of the Regulation. According to what stated in the above mentioned articles, Pharmaceutical Companies should have submitted by the 26th of January 2008 a list of all existing and completed paediatric studies; this obligation applies to **all** authorised medicinal products, regardless of the existence of a paediatric indication. The studies should have been submitted using the xls template agreed among all Member States, after consultation with the EMEA and the European associations of Pharmaceutical Industry; if necessary, the annex also should be filled in and submitted.

It is reminded to all MAH who have not yet submitted the above mentioned templates, to comply immediately with this requirement. The EMEA will accept the templates sent as a response to this urgent reminder.

The templates for Italy should be sent to the following email address: paediatrics@aifa.gov.it. No paper copies are required at the moment.
For any further information, Applicants can consult the procedural guidance, that is published in this section or visit the CMDh website (www.hma.eu/cmdh.html).
For any further clarification from the AIFA, Applicants are also suggested to contact dr. Gabriella Conti (g.conti@aifa.gov.it) or dr. Sandra Petraglia (s.petraglia@afa.gov.it).