European Medicines Agency
Pre-authorisation Evaluation of Medicines for Human Use

London, 23 June 2005
Doc. Ref. EMEA/196218/2005

Note of Explanation to accompany publication of Reflection Paper on Formulations of Choice for the Paediatric Population (EMEA/CHMP/PEG/194810/2005)

This reflection paper was produced with two main aims:-

a. to provide general information or 'points to consider' for those in the pharmaceutical industry who may have little experience of the issues when formulating medicines for children, and

b. to serve as the precursor to a guideline on the subject by stimulating those with most experience to contribute their additional and more specific information, experience and opinion to the framework presented.

Readers are requested to provide comments on the document from both perspectives. In particular, we will be pleased to receive comment on the information that could and should be included in guidelines concerning formulation of paediatric medicines. It is recognised that several guidelines may be required to cover this subject.

Whilst the objective of this document is to encourage the pharmaceutical industry to develop authorised ready-made paediatric dosage forms which do not need such manipulations, the CHMP recognises that until such time as medicines which are clearly useful in paediatric patients are legitimately authorised and presented in a suitable form for this population, there will remain a gap where pharmacists and caregivers may need to manipulate adult medicines in exceptional cases, for the benefit of paediatric patients.

Therefore, a further aim has been to highlight the risks attached to these manipulations and readers are requested to comment on the way in which the pharmaceutical industry and practitioners might make such manipulations safer and more effective.

Please comment on the following questions:

a. does the document serve the purpose to inform those in the pharmaceutical industry who may have a need for information about formulations for children?

b. what specific or detailed information should be added (or removed) when preparing an EMEA guideline on formulations for children?

c. How can the pharmaceutical industry contribute to safer and more effective use of authorised dosage forms

   i. when children have difficulty with the administration of dosage forms authorised for them?

   ii. when authorised dosage forms are used 'off-label' for children?

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 85 45
E-mail: mail@emea.eu.int http://www.emea.eu.int