

Villejuif, November 30th, 2008

Comments by ITCC and SIOPEurope on the :

Concept paper on the development of a quality guideline on pharmaceutical development of medicines for paediatric use (EMA/13891/2008)

Dear Sir,

We read with interest the concept paper proposal issued by EMA for the development of a quality guideline on pharmaceutical development of medicines for paediatric use.

ITCC and SIOPE strongly support the principles and proposals that are outlined in this draft document.

Indeed, there is a lack of age-appropriate paediatric formulations for most of the cytotoxic anticancer drugs being used orally on a regular basis either in front-line therapies, in relapse treatments or for palliative intent. This is particularly true for compounds such as etoposide, cyclophosphamide, temozolomide and 6 mercaptopurine.

We have already highlighted this need through our comments on the revised priority list for studies into off-patent paediatric medicines Ref EMA 226983/2008, on July 4th, 2008. Indeed, to provide young children with appropriate oral formulation of off-patents anticancer drugs that fulfil all recommendations of quality should be a major objective in the next years.

To this extent we would like to highlight the need to consider protection of parents, patients and people in the environment when toxic compounds, such as cytotoxic anticancer drugs, are to be delivered orally to children at home.

In addition, most of the new targeted anticancer drugs that are currently approved or under development are oral medicines to be used through protracted schedules of administration. It is crucial that age-appropriate formulations are developed for those compounds as well, through the highest quality processes, in order to provide children with medicines that will be easy to take. Innovation in drug formulation and in dosing device should be encouraged.

ITCC and SIOPE remain fully committed to participate to the development of safe and effective drugs for children with cancer.

Kind regards

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