EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Health systems and products
Medicinal products – authorisations, European Medicines Agency

PHARM 649

PHARMACEUTICAL COMMITTEE
26 March 2014

Subject: **Paediatrics: Best practices to promote at national level clinical trial research with children**

Agenda item 4

The Paediatric Regulation intends to stimulate clinical research with children in order to increase the number of authorised medicinal products that have been specifically developed and tested for children.

The low number of paediatric patients in certain disease areas constitutes however, an obstacle for paediatric clinical research and development. Sponsor of clinical trials report recruitment issues that lead to delayed completion of trials or underpowered results. Physiological differences of children of various ages make it necessary to include certain minimum patient numbers of different age-subsets in clinical trials, thus worsening recruitment difficulties.

At the same time, it is important to recognise the sensitivity of such research in view of the specific vulnerability of this age group and the specific situations of parents and young patients who are confronted with difficult choices, including the decision whether to participate in a trial or not.

In view of those specificities, the Commission would like to know whether Member States have taken measures in recent years to improve knowledge about paediatric clinical research and raise awareness about the importance of clinical trials for the development of medicines for children, either targeting the general public or specifically children and parents. Some best practises could inspire other Member States by building on existing experience.

If Member States have experience in this regard, they are invited to send a short description of the measures they have taken or the projects they have supported at national level by email to sanco-pharmaceuticals-D5@ec.europa.eu by 19 March 2014, at the latest. Depending on the feedback received, the Commission may ask some of the respondents to present their activities to the other Committee members.

Action to be taken:

For follow-up/discussion