EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Health systems and products
Medicinal products – authorisations, EMA

PHARM 627

PHARMACEUTICAL COMMITTEE
23 October 2013

Subject: **Better medicines for children – The Commission report on the Paediatric Regulation – The 10-year report in 2017**

Agenda item 1

In June 2013 the Commission published a progress report on medicines for children covering the first five years since the Paediatric Regulation (Regulation (EC) 1901/2006) came into force. This preliminary snapshot points to improvements in the paediatric medicines landscape: better and safer research**,** more medicines for children on the EU market and more information for parents and health professionals**.** Although it will take at least another five years for the full impact of the legislation to be understood, due to the long development cycles for medicines, the EU commitment to better medicines for children is clear.[1]

The main findings of the report will be presented to the Pharmaceutical Committee.

Moreover, for the Regulation to be a success, it is of importance that new information on paediatric uses is appropriately communicated to, and used by paediatricians in their day-to-day work. In the Commission's view national competent authorities as well as organisations for healthcare professionals seem particularly qualified to consider an adequate flow of information. Delegates are invited to consider appropriate action.

In addition to that, it is generally accepted that the Paediatric Regulation will lead to more clinical trials with children, but that its aims should be achieved without subjecting children to unnecessary clinical trials. Pharmaceutical companies still report recruitment difficulties for trials they sponsor in the EU. The Commission would be interested to learn whether Member States have set up programs or can report best practices to support clinical studies in children participation-wise.

[1] http://ec.europa.eu/health/files/paediatrics/2013_com443/paediatric_report-com(2013)443_en.pdf.

The 2013 report will be followed by a more comprehensive report scheduled for 2017. The Commission would like to share with the Pharmaceutical committee the planning as regards this second report.

Action to be taken:

For Discussion/Information