EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Health systems and products
Medicinal products – authorisations, EMA

PHARM 664

PHARMACEUTICAL COMMITTEE
22 October 2014

Subject: **Paediatrics: "Road to 2017"**

Agenda item 5

In 2013 the Commission published a first progress report on **the Paediatric Regulation** (Regulation (EC) 1901/2006). This report will be followed by a more comprehensive report to be presented to the European Parliament and the Council in 2017. This second report should assess the impact and performance of the Regulation from a public health and an economic perspective.

In order to prepare this report and take informed decision, the Commission is currently considering the following actions until 2017:

- Economic analysis with support of an external study
- Public health impact on the basis of data collected by EMA
- Collect information of stakeholder experience
- Seek views of regulators
- Compare the EU achievements with what has been achieved in the US.

In this context, the Commission would be interested in learning whether Member States have commissioned studies or have data available on the following topics, which could be shared with the Commission:

- Number of adverse drug reactions in children (e.g. compared to adults)
- Development of prices of paediatric medicines in recent years
- Costs of paediatric trials in the EU
- Off-label prescribing in the paediatric population

Action to be taken:

For discussion/information