EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

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

PHARM 694

**PHARMACEUTICAL COMMITTEE**
**21 October 2015**

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

**Agenda item 4**

In 2013 the Commission published a first progress report on **the Paediatric Regulation** (Regulation (EC) 1901/2006). It 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 decisions, several actions are planned, including:

- An external study analysing the economic impact of the Paediatric Regulation with specific focus on rewards and incentives;
- A detailed account prepared by the European Medicines Agency on health related indicators with regard to paediatric medicines;
- A US-EU workshop on respective experience with the regulatory framework on paediatric medicines;
- A public consultation;
- Regular updates on progress in the Pharmaceutical Committee.

**Action to be taken:**
For information