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HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

Health systems, medical products and innovation
Medicines: policy, authorisation and monitoring

PHARM 709

PHARMACEUTICAL COMMITTEE
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Subject: **Paediatrics**

Agenda item 4i

Update on the preparation of the Commission report on the Paediatric Regulation

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

As explained to the Pharmaceutical Committee in October 2015 several actions are currently under way and/or planned in order to prepare the report. This includes:

- A study, commissioned by the European Commission regarding the economic impact of the Paediatric Regulation (to be finalised in Q3/2016);
- A detailed account prepared by the European Medicines Agency on health related indicators with regard to paediatric medicines;
- A bilateral meeting between the US and EU regulators to discuss experience with and perspectives of the regulatory framework for paediatric medicines;
- A public consultation in the second half of 2016.

The Commission will provide the Committee with an update on the state of play of those actions.

Action to be taken:
For information