



EUROPEAN COMMISSION  
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

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

PHARM 718

**PHARMACEUTICAL COMMITTEE**  
**18 October 2016**

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**Subject: Paediatrics**

**Agenda item 4i**

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**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.

On 19 September 2016 the Commission met with experts from Member States and the European Medicines Agency to discuss their experience with the Paediatric Regulation.

The Committee will be debriefed about the outcome of this meeting. Additionally, an update on the state of play of the preparatory work, including the public consultation (to be launched in Q4/2016) will be provided.

**Action to be taken:**

For information