



EUROPEAN COMMISSION  
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Health systems and products  
Medicinal products – authorisations, EMA

PHARM 631

**PHARMACEUTICAL COMMITTEE**  
**23 October 2013**

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**Subject: Legal and Regulatory news**

**Agenda item 3b**

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➤ **New regulatory texts published**

The following regulatory texts have been published since the last meeting of the Pharmaceutical Committee:

- Notice to applicants, medicinal products for human use, [volume 2A, chapter 1](#) marketing authorisations
- [Variation guidelines](#) – guidelines on the details of the various categories of variations

➤ **Ongoing public consultations/Commission calls**

- Commission call for expression of interest for the position of civil society representative in the Paediatric Committee
- Public consultation on Commission guidelines concerning the format and content of paediatric investigation plans

**Action to be taken:**

For information