

Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004 (Text with EEA relevance)

TITLE VI

COMMUNICATION AND COORDINATION

Article 43

1 On the basis of the information referred to in Article 42 and after consulting the Commission, the Member States and the interested parties, the Paediatric Committee shall establish an inventory of therapeutic needs, in particular with a view to identifying research priorities.

The Agency shall make the inventory public at the earliest by 26 January 2009 and at the latest by 26 January 2010 and shall update it regularly.

2 In establishing the inventory of therapeutic needs, account shall be taken of the prevalence of the conditions in the paediatric population, the seriousness of the conditions to be treated, the availability and suitability of alternative treatments for the conditions in the paediatric population, including the efficacy and the adverse reaction profile of those treatments, including any unique paediatric safety issues, and any data resulting from studies in third countries.