Medicinal products for paediatric use

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The committee adopted the report by Françoise GROSSETÊTE (EPP-ED, FR) broadly approving, under the 2nd reading of the codecision procedure, the Council's common position on the proposed regulation on medicinal products for paediatric use. MEPs nevertheless adopted a number of amendments, as follows:

- it should be specified that Article 95 (internal market) constitutes the legal basis for the regulation;

- in order to guarantee the independence of the Paediatric Committee, its members should "not have financial or other interests in the pharmaceutical industry which could affect their impartiality, should undertake to act in the public interest and in an independent manner, and should make an annual declaration of their financial interests";

- a 1st reading amendment was reintroduced providing for the opinion of the Paediatric Committee to be made public;

- one amendment sought to ensure that marketing authorisations for medicinal products for adults are not delayed, while at the same time taking due account of the importance of the specific paediatric studies which applicants will be obliged to conduct;

- a 1st reading amendment was retabled making it obligatory (rather than leaving it to the discretion of the competent authority) to set up a risk management system where marketing authorisation is granted for a paediatric indication;

- regarding the need to encourage the pharmaceutical industry to invest in new medicines, the committee adopted a transitional clause stating that, for five years after the regulation enters into force, "the application for an extension of the duration of a certificate already granted shall be lodged not later than six months before the expiry" of a Supplementary Protection Certificate. MEPs felt it was important to introduce this clause given that there are currently medicinal products whose certificate is due to expire but which may be important for the paediatric population.