Medicinal products for paediatric use

2004/0217(COD) - 07/09/2005 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted a resolution drafted by Françoise GROSSETÊTE (EPP-ED, FR) and made several amendments to the Commission's proposal. The main point of debate involved the best way to give incentives to pharmaceutical companies to invest more money in paediatric medicine. The Commission proposed that companies should have an extra six months of protection under existing patents. A number of Members wanted to have a shorter additional period or one which depended on the size of the company. The rapporteur was firmly in favour of a fixed period. Some member states had argued for a shorter extension, in order to support their generic drug manufacturers. A review clause states that this point should be reassessed six years after the Regulation enters into force.

The remaining amendments mostly relate to the following:

-many amendments aim to shorten procedures and administrative delays, to improve transparency and the exchange of information to prevent unnecessary clinical trials;

-Parliament felt that a specific inventory of paediatric medicinal product needs must be adopted by the Paediatric Committee set up under the Regulation after consultation with the Commission, the Member States and interested parties, and regularly updated. The inventory should identify the existing medicines used by children and highlight the therapeutic needs of children and the priorities for research and development. In this way, companies should be able to identify easily opportunities for business development; the Paediatric Committee should be able to better judge the need for medicines and studies when assessing draft paediatric investigation plans, waivers and deferrals; and healthcare professionals and patients should have a reliable information source available to support their decisions as to which medicines to choose.

-A new Chapter 1a on identification of needs is inserted. The Agency must publish the inventory within two years of the entry into force of the Regulation and update it regularly, including the data from trials carried out in third countries. This inventory will also be aimed at establishing research priorities.

-Within one year of the entry into force of the Regulation, the Management Board of the Agency will adopt an implementing strategy for the launching and operation of the European network. This network must be compatible with the work of strengthening the foundations of the European Research Area in the context of the Community Framework Programmes for Research, Technological Development and Demonstration Activities.

-the Paediatric Committee must be independent of the pharmaceutical industry and be composed of members with recognised and documented international-level experience and knowledge of that industry.

-In view of the fact that 50% of medicinal products for paediatric use have not been tested, provision is made for funding for research on medicines for paediatric use which are not patent-protected or do not have supplementary protection certification to be financed under Community research programmes. Parliament wished to establish a Community programme for research into medicinal products for children (Medicines Investigation for the Children of Europe - MICE).

-Details of the results of all completed studies conducted in accordance with an agreed paediatric investigation plan, whether terminated prematurely or not, as well as details of the results of all studies funded by the Community and the Member States to support research into and the development and availability of medicinal products for paediatric use, including any studies funded by the MICE

programme, will be published by the Agency with, whenever applicable, all relevant conclusions for medicinal products in the same therapeutic class that cover the same proposed paediatric use.

-There should be a European register of clinical trials of medicinal products for paediatric use. Such studies should also be entered in the databases of clinical investigations currently in operation at national level. Studies in children already performed in third countries should not be repeated. However, if unavoidable, control studies should be possible.

-There are some additional clauses on pharmacovigilance matters;

-An application for an extension of the duration of a certificate must be lodged not later than six months before the expiry of the certificate, rather than two years.

-If a medicinal product is authorised for a paediatric indication and the marketing authorisation holder has benefited from the incentive provisions in the Regulation, if the marketing authorisation holder discontinues placing the medicinal product on the market, the holder must allow a third party to use the pharmaceutical, pre-clinical and clinical documentation contained in the file on the medicinal product.

-The Commission must carry out an analysis of the incentive and reward operations under Articles 36 and 37, with a financial assessment relating to the research costs and profits resulting from such incentives. Should the analysis show the mechanism to be ill-suited to the results sought or achieved, an amendment of the articles will be proposed.