Medicinal products for paediatric use

2004/0217(COD) - 12/12/2006 - Final act

PURPOSE: to lay down rules concerning the development of medicinal products for human use in order to meet the specific therapeutic needs of the paediatric population.

LEGISLATIVE ACT: Regulation (EC) No 1901/2006 of the European Parliament and of the Council 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.

CONTENT: The Council adopted this Regulation on medicinal products for paediatric use and approved all the amendments passed by the European Parliament at second reading. The Regulation is aimed to address the current situation in Europe, whereby more than 50% of the medicines used to treat children have not been tested and are not authorised for use on children. The health and therefore quality of life of the children of Europe may suffer from a lack of testing and authorisation of medicines for their use.

The Regulation aims to improve child health, by increasing the availability throughout the Community of medicinal products that have been appropriately tested and authorised for paediatric use, while removing obstacles to intra-Community trade in paediatric medicinal products. The Regulation aims in particular to meet the following objectives:

- to ensure that medicinal products used to treat children have been the subject of ethical high-quality research and appropriate clinical trials;

- to ensure that those medicinal products are duly authorised;

- to improve information on the use of medicinal products intended specifically for children and transparency on paediatric clinical trials, while avoiding unnecessary clinical trials on children and delays on the authorisation of medicinal products for other age populations.

To that end, the Regulation contains a combination of obligations and incentives.

The main obligation created by the Regulation is that either the results of clinical studies obtained in accordance with a paediatric investigation plan, or proof of having obtained a waiver for medicines that are of no paediatric use, must be submitted as part of the procedure for obtaining marketing authorisation. For medicines protected by a patent or an SPC, incentives are provided through the extension of exclusive rights. The regulation also aims to certify a safe use of off-patent medicinal products for the treatment of children, through the introduction of a new type of marketing authorisation for off-patent medicines that have been appropriately tested for paediatric use, the PUMA, as well as through provisions on funding of research into the appropriate use of off-patent medicinal products for paediatric treatment.

A scientific committee, the Paediatric Committee, is created within the European Medicines Agency, with expertise and competence in the development and assessment of all aspects of medicinal products to treat paediatric populations.

The proposed system covers medicinal products for human use within the meaning of the directive on the Community code relating to medicinal products for human use and is in full compliance with the EU clinical trials directive.

In order to fulfil its objectives, the new Regulation also introduces some amendments to the regulation that created a supplementary protection certificate for medicinal products, the directive on the Community code relating to medicinal products for human use, the regulation laying down procedures for the authorisation and supervision of medicinal products and the EU clinical trials directive.

In a Declaration, the Commission states that, in view of the risks of carcinogens, mutagens and substances toxic to reproduction, it will request the Committee for Medicinal Products for Human Use of the European Medicines Agency to draw up an opinion on the use of these categories of substances as excipients of medicinal products for human use, on the basis of Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.

The Commission will transmit the opinion of the Committee for Medicinal Products for Human Use to the European Parliament and the Council. Within six-months of the opinion of the Committee for Medicinal Products for Human Use, the Commission will inform the European Parliament and the Council of any necessary action it intends to take to follow-up on this opinion.

ENTRY INTO FORCE : 26/01/2007. Article 7 is applicable from 26/07/2008. Article 8 is applicable from 26/01/2009. Articles 30 and 31 are applicable from 26/07/2007.