Medicinal products for paediatric use

2004/0217(COD) - 01/06/2006 - Text adopted by Parliament, 2nd reading

The European Parliament adopted a resolution drafted by Françoise **GROSSETÊTE** (EPP-ED, FR) on the new rules framing the marketing of medicines for children. A series of compromise clauses were negotiated with the Council and Commission. The law will cover medications currently in development and not yet authorised, authorised medications covered by patents as well as authorised products that are not covered by intellectual property rights. The Regulation will require pharmaceutical companies to draw up "paediatric investigation plans" (a research and development programme aiming at guaranteeing the necessary data for those who require paediatric treatment) before filing authorisation requests for new medicines intended for children. In exchange, the duration of supplementary protection certificates (an intellectual property right) will be extended by six months. The same reward, subject to the same conditions, will also be available for medicines already on the market and still covered by intellectual property rights.

The other main points of the compromise agreement are as follows:

Legal base: Parliament stated that any action to promote the development and authorisation of medicinal products for paediatric use is therefore justified with a view to preventing or eliminating these obstacles. Article 95 of the Treaty is therefore the proper legal basis.

Committee independence: In line with Parliament's demands, the compromise enhances the independence of the Paediatric Committee. It therefore states that Members of the Paediatric Committee 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. This Committee, established within

the European Medicines Agency (EMEA), will be responsible for assessing and approving the 'paediatric investigation plans' which should accompany requests for authorisation for the marketing of new drugs. The institutions have also agreed that the opinions of the Paediatric Committee should be made public. Between two and three years after entering into force the Paediatric Committee will draw up an inventory of therapeutic benefits in order to determine research priorities.

Substances that are carcinogenic, mutagenic or toxic for reproduction: A statement from the Commission indicates that, in view of the risks of carcinogens, mutagens and substances toxic to reproduction, the Commission will request the EMA 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 Articles 5(3) and 57(1)(p) of Regulation 726/2004/EC. 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 the Commission will inform the European Parliament and the Council of any necessary action it intends to take to follow up on this opinion.

Supplementary protection certificates: the Council text on the duration of the extension of supplementary protection certificates still stands. Parliament had proposed that extensions should only be granted from the time when a medicine has received authorisation for marketing in all the member states. The Council recommended the extension of SPCs immediately a product is authorised in all the member states and if relevant information on the results of studies is included in product information: this is the provision finally retained. The difference is significant since there is often a considerable gap between the moment when a medicine is authorised and the time it effectively reaches the market. Parliament approved a transitional clause which states 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 expiryof a Supplementary Protection Certificate.

The risk management system: where there is particular cause for concern, the competent authority shall require, as a condition for granting marketing authorisation, that a risk management system be set up or that specific post-marketing studies be performed and submitted for review.