Medicinal products for paediatric use

2004/0217(COD) - 02/06/2005

Pending receipt of the European Parliament's opinion, the Council held a policy debate on the proposal for a Regulation on medicinal products for paediatric use with a view to further examination of the text.

The debate focused on the following two questions:

– extension of the validity of the supplementary protection certificate, as a way of encouraging investment in pharmaceutical products for paediatric use;

– allowing public access to data on paediatric clinical trials in order to avoid unnecessary paediatric clinical trials.

During the debate, particular emphasis was placed on the importance of encouraging research in this field and improving access to paediatric medicines, in view of the need to produce medicines adapted to the specific physical and psychological characteristics of children.

The delegations recognised the incentive value of a measure extending the protection certificate. Some of them, however, wanted to discuss the proposal further, in particular the length of the extension1 and the date on which the impact of the mechanism would be reviewed, given the less positive effects that such a measure might also produce (e.g. delay in the placing on the market of generic medicines).

Delegations were generally in favour of making the results of clinical trials more widely available, as this would help to avoid unnecessary clinical trials, but further discussion was needed to establish, in particular, how widely available this would mean.