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## Paediatric drugs in Europe

### Motion for a recommendation

tabled by Mr Bernard MARQUET and other members of the Assembly

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This motion has not been discussed in the Assembly and commits only those who have signed it

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To date there are very few paediatric medicines, and research and clinical trials on paediatric medicines are non-existent.

This deficiency is due to the fact that the pharmaceutical industry considers the market too small, and therefore unprofitable.

The cost of research and development is not recouped because of the small number of children in each age group affected by each disease. Moreover, the difficulties of pharmaceutical development appropriate to children and the problems of carrying out clinical trials on children exacerbate this situation.

Clinical research involving children should, for reasons of ethics and medical safety, be carried out only on a subsidiary basis, on a limited scale, in cases where it is strictly impossible to carry it out by any other means, in particular by transposing or using as a model tests conducted on adults.

Lastly, it is often difficult to obtain parents' informed consent, which is compulsory in the case of a minor.

Overall, however children (0 to 16 years) account for 20% of the population of the Council of Europe, numbering 160 million.

At the moment, medicines are very often prescribed outside the terms of the marketing authorisation, whereas it seems obvious that children should benefit from treatments evaluated in terms of efficacy and tolerance, as is the case for adults.

Since the Paediatric Research Equity Act (PREA) was passed in the United States in 2003, all American biopharmaceutical companies have been required to test their new medicines to ascertain their safety and determine their effectiveness and dosage for children. This will entail an increase in the number of clinical trials undertaken on the paediatric population.

The Parliamentary Assembly of the Council of Europe therefore invites the governments of the member states of the Council of Europe to take the measures needed to harmonise the legal framework governing clinical trials involving children, in order to make them compulsory, but subject to safety measures.

It also invites the pharmaceutical industries to develop research and clinical trials on paediatric medicines and to co-operate closely with one another.

The Parliamentary Assembly points out that this issue comes within the scope of the action plan adopted at the 3rd Council of Europe Summit and the three-year programme "Building a Europe for and with Children", which the Council of Europe launched in Monaco on 4 and 5 April 2006.

*Signed (see overleaf)*



*Signed*<sup>1</sup>:

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1. ALDE: Alliance of Liberals and Democrats for Europe  
EPP/CD: Group of the European People's Party  
SOC: Socialist Group