COMITÉ PERMANENT DES MÉDECINS EUROPÉENS
STANDING COMMITTEE OF EUROPEAN DOCTORS

CPME/AD/Brd/121104/140/EN

At its Board meeting in Göteborg, Sweden, on 12 November 2004, the CPME adopted the following policy : Proposed regulation on medicines for paediatric use: CPME response (CPME 2004/140 Final EN/fr)

Proposed regulation on medicines for paediatric use: CPME response

The Standing Committee of European Doctors (CPME[1]) warmly welcomes the proposed regulation as a significant step forward in improving the health of Europe's children and ensuring their safety when they undergo medical treatment. This is an important initiative, and we urge all those involved to support it and to ensure that it is adopted and implemented as rapidly as possible.

While giving this proposal our wholehearted support, we recognise that it will take many years to develop a full range of medicines specifically adapted for children. Until then doctors treating children will need to continue to use their clinical judgement in prescribing and must retain the flexibility to do so, to ensure that children with life threatening and rare conditions are not deprived of effective treatment. Clearly, research involving babies and children who may not be able to consent to involvement on their own behalf raises ethical questions. Any such research would need to be subject to rigorous ethical scrutiny. The CPME emphasizes the essential role of academic research on paediatric medicines. Such research should be encouraged by means of incentives for those who fund it.

[1] *The Standing Committee of European Doctors (CPME) is the representative body of about 2 million physicians in Europe.*

Its aims are:

- *to promote the highest standards of medical training and medical practice, through advocating:*
  - *public health,*
  - *the relationship between patients and doctors*
  - *the free movement of doctors and patients within the European Union*
- *to achieve the highest quality of health care in Europe.*

It is composed of the most representative non-governmental national medical organisations in EU/EEA countries, that is to say 26 National Medical Associations. It also unites associated members, observers and associated organisations (specialised European medical organisations).

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We also suggest that, as a transitional measure, the European Commission consider the immediate granting of incentives for research into paediatric medicines. This would encourage those companies with an interest to start working in this area immediately, rather than waiting until the legislation is adopted.

Although it is not part of the proposed regulation, we also endorse the move to set up a study programme – Medicines Investigation for the Children of Europe (MICE) – to promote studies into the paediatric use of medicines not covered by patents or supplementary protection certificates. We urge the Commission to make this a priority and to ensure that it is fully funded and supported. The ethical principles that should apply in this situation must be as rigorous as in the cases referred to above.

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