THE COUNCIL OF THE EUROPEAN UNION,

(1) RECALLS that a high level of health protection is to be ensured in the definition and implementation of all Community policies and activities and that Community action, complementing national policies, is to be directed towards improving public health, preventing human illness and diseases, and obviating sources of danger to human health.

(2) NOTES that nearly 20 % of the Community population, i.e. 75 million people, is under the age of 16.

(3) NOTES that, as regards their treatment, children have characteristics which vary with their age and which mean that in most cases they cannot be treated like adults. In particular, a medicinal product administered to a child has specific characteristics in terms of pharmaco-kinetics, effectiveness and undesirable effects. Furthermore, a medicinal product intended for children requires appropriate pharmaceutical presentation, to ensure easy and safe administration.

(4) NOTES that a large number of the medicinal products administered to children have not been assessed specifically for paediatric use and may therefore not meet the criteria of quality, safety and effectiveness required in the case of adults.

(5) OBSERVES that the prescription of medicinal products to children is therefore very often not covered by the marketing authorisation and that, taking into account the shortage of paediatric pharmaco-vigilance data, safety of use in this population group cannot therefore be documented by monitoring studies after marketing.

(6) RECOGNISES that making paediatric medicinal products available involves difficulties of pharmaceutical development and of clinical development. The necessary research and development costs are not amortised because of the small number of children affected by each disorder in each age bracket.

(7) CONSIDERS that the development of paediatric medicinal products and clinical trials involving children may give rise to specific ethical concerns and that children must benefit from special protection.

(8) CONSIDERS that all Member States face this problem and that a European approach offers advantages from the epidemiological, public health and economic points of view.

(9) ACCORDINGLY INVITES THE COMMISSION to make appropriate proposals as soon as possible in the form of incentives, regulatory measures or other supporting measures in respect of clinical research and development, taking account of the ethical aspects of clinical trials on children, to ensure that new medicinal products for children and medicinal products already on the market are fully adapted to the specific needs of that population group, and taking into account also the internationally acknowledged standards for the protection of minors with regard to medical scientific research.