COMITÉ PERMANENT DES MÉDECINS EUROPÉENS
STANDING COMMITTEE OF EUROPEAN DOCTORS

CPME/AD/Exec/120602/13/EN/fr

At the request of the CPME Executive Committee (emergency issue), Brussels, 12th June 2002, the CPME adopted the following policy : **CPME points in response to the Commission consultation document "Better medicines for children** (CPME 2002/063 EN/fr)

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Consultation

Better medicines for children, proposed regulatory actions on paediatric medicinal products.

The proposals set out in the consultation document correspond very closely to those adopted unanimously by the Council of Health Ministers at Nice in December 2000. Actually, those proposals, which were drawn up in response to a French initiative, drew heavily on a package of measures introduced in the United States in 1997-98, known as the *Paediatric Rule*. These provisions present a number of similarities with successive measures introduced in the United States and the EU in respect of orphan diseases, aimed at facilitating the market availability of diagnostic tests and medicines for these conditions which are frequently cold-shouldered by the industry for their low return-on-investment potential. The provisions governing "orphan diseases" are, of course, laid down in European rules.

The measures proposed as part of the action plan on "paediatric medicinal products" have been put out to wide-ranging consultation among European specialist interests, in particular paediatricians and pharmacologists specializing in paediatric medicines. The industry, national medicines control agencies and the EMEA have also been consulted. There is a very broad consensus on the desirability of the measures proposed, and the fundamentals of the regulatory system they would entail. This being the case, CPME can only encourage the Commission to put its proposals into practical form at the shortest possible term.

However:

1 - In 2001, the FDA carried out and published a status report on the *Paediatric Rule*, which is in fact a mixed set of mandatory and incentive measures for the pharmaceutical industry. Unless good grounds are shown for doing otherwise, all new medicinal products for which marketing authorization is sought had to have undergone appropriate clinical trials in children at various stages of their physiological development. Incentives (e.g., extensions of patent protection) were provided to encourage manufacturers of medicines already on the market to conduct paediatric research, although this, unlike the provisions applicable to new medicinal products, was not compulsory. Overall, the mandatory rules proved highly effective, although failing to yield a sufficient volume of new information of real use to paediatric practice, whereas the incentive measures were judged disappointing, and in any event failed to live up to initial expectations.

For that reason, President Bush signed the *Best Pharmaceuticals for Children Act* in January 2002, authorizing the grant of public funds via the NIH to independent research agencies run by the pharmaceutical industry in particular. At the same time, the *Paediatric Rule* was to be amended.

2 - It is hardly surprising, therefore, that the European pharmaceutical industry, in particular via EFPIA, should be trying to get provisions more favourable than those initially floated, which are now recognized as inadequate in the United States where they have been tried out since 1998. The Commission itself, indeed, has admitted that purely incentive measures do not work properly, and so the creation of a publicly financed fund to support research into paediatric medicines is now being mooted.

3 - It has to be emphasised however that the treatment of children wherever possible should be done with medicines of which the use and effects should be monitored and documented and may be considered for further regulatory decisions.
The availability of paediatric studies for new drugs alone is no argument to use them. Physicians should not be driven to substitute well-known treatments unless an improvement in treatment could be clearly established.

4 - Publication of data collected in the course of using established drugs or when testing new drugs are mandatory (see Declaration of Helsinki, The World Medical Association, 2000). Commercial interests of pharmaceutical companies are secondary to the protection of our patients, adults or children. Currently CPME finds there is a lack of transparency in the operation of the European agency, EMEA.

The Standing Committee of European Doctors (CPME) favours the Commission's proposal for a publicly financed fund. The fund is thought to support research on paediatric medicines, because research so crucial to public health should not be exclusively tied to the interests of the pharmaceutical industry, which are - however legitimate and understandable they may be - largely commercial interests. Ideally, specialist networks that should ensure that pharmaceutical studies do not duplicate similar previous research should perform this research.

CPME is a membership driven association. The members are National medical associations (NMAs) of the EU member states and the EFTA countries. CPME has as observers and associate members NMAs from other European countries, many of them applicant countries to EU. CPME represents 1,4 million doctors within the EU/EEC. CPME's aim is to promote the highest standards for public health and medical practice at the EU level.