COMITÉ PERMANENT DES MÉDECINS EUROPÉENS
STANDING COMMITTEE OF EUROPEAN DOCTORS

CPME/AD/Exec/040702/15/EN

At the request of the CPME Executive Committee (emergency issue), Brussels, 4 July 2002, the CPME adopted the following policy : **CPME comments on the proposal for a regulation of the EP and the Council laying down Community procedures for the authorisation and supervising of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal products (COM(2001)404)** (CPME 2002/071 EN)

CPME comments on MEP Müller's report, rapporteur on the proposal for a regulation of the European Parliament and of the Council laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal products (Com (2001) 404)

The EU Commission embarked on a vast task when it decided to review the EU pharmaceuticals legislation with a view to reforming EU legislation on medicinal products.

One of CPME primarily concerns is the safety, effectiveness, and quality of medicinal products which are prescribed to patients.

As such, CPME welcomes the fact that pharmacovigilance is reinforced and strengthened in this Commission's proposal. Allowing the possibility of a rapid withdrawal of medicinal products and waving the renewal of marketing authorisations every 5 years is thus balanced with a strong pharmacovigilance procedure.

MEP Müller proposes it should be possible for adverse reactions to be reported not only by health care professionals but also directly by patients themselves via a report form that would be in the package of the medicinal products (amendment 17, Article 20 paragraph 3).

Although CPME is very much in favour of any initiative to increase information and reporting on medicinal products it opposes this proposition. The justification given by MEP Müller that "*many doctors are too busy to record and forward to the appropriate authorities details of a large number of minor adverse reactions*" does not hold ground. It deplores the fact that the alleged information, which leads to the justification, is missing.

Aside from that CPME is of the opinion that pharmacovigilance is an important task for the doctor and should be part of a quality system that helps guarantee the best possible care for a patient.

MEP Müller's amendment and its justification that "*Serious shortcomings have been observed in the dissemination by health care professionals of information about adverse reactions*" are attacks against the conscientiousness of doctors, again without any background documentation.

The Commission proposes the preparation of guidance by the "*Commission in consultation with the Agency, Member States and interested parties*".

MEP Müller suggests adding "*Such guidance shall lay down rules of conduct for health care professionals concerning the targeted dissemination of information about adverse reactions which have occurred in practice*" (Amendment 20, Article 24 paragraph 1).

CPME is willing to reflect and take part in the drafting of guidelines to help in the handling of adverse effects of medicinal products. With regard to the importance of the relationship Doctor/patient, CPME would like to see the medical profession included formally and officially in the consultation.

CPME wants to reassert solemnly that the patient and patient's health are always at the centre stage of the doctor's preoccupations.

CPME is in favour of a strong pharmacovigilance where the medical profession is a member of the key stakeholders.