COMITÉ PERMANENT DES MÉDECINS EUROPÉENS
STANDING COMMITTEE OF EUROPEAN DOCTORS

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At the CPME Board Meeting in Brussels on 13 June 2009, CPME adopted the following document: "**CPME reaction to Commission paper Proposal for a legislation amending Directive 2001/83/EC on the Community code relating to medicinal products for human use**" (CPME 2009/093 final EN/Fr)" (referring to CPME 2009/093 EN/Fr)

CPME reaction to Commission paper *Proposal for a legislation amending, as regards pharmacovigilance, Directive 2001/83/EC on the Community code relating to medicinal products for human use (COM(2008) 665, 10th December 2008 and related documents (COM(2008) 664)*

CPME is the Community Representative of all members of the medical profession. We feel therefore not competent to discuss the wording of individual legal changes as proposed by the Commission. CPME previously reacted to the Public Consultation of May 2006: Suggestions to improve and strengthen the Community pharmacovigilance system (CPME 2006/13).
We will therefore put the proposed amendments into the scope of changes that we proposed in our statement CPME 2006/133 and CPME 2008/004
In our reply to the Commission we suggested:

- The setting up a quality system to assess the pharmacovigilance system and actions taken.
- Relevant information should be collected on the impact of actions taken amongst prescribers.
- A structure should be developed that will assist independent studies conducted on pharmacoepidemiology, pharmacoeconomics and social pharmacology by scientific societies, professional associations and academic investigators. Assistance, at a technical and economic level, will strengthen these studies.
- A highly qualified experts' group on drug safety should be created. Furthermore, a professional initiative should be set up to train these professionals, including disciplines of a pharmacological nature, experts from public administration and the academic field. Member States have to supply funds whereas national physicians associations shall be responsible for organizing the education of physicians in pharmacovigilance. This must be a task of national associations as well as academia, where Pharmacovigilance should become a mandatory subject as a part of teaching clinical and experimental pharmacology

The present proposals of the Commission aim at pinpointing concrete propositions to change the legal system of the Community in order to improve EU-wide pharmacovigilance.

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We agree with the Commission that pharmacovigilance is a key public health function. It comprises indeed:

- Collecting and managing data on the safety of medicines
- Looking at the data to detect "signals"
- Evaluating the data and making decisions with regard to safety issues
- Acting to protect public health (including regulatory action)
- Communicating with stakeholders
- Audit, both of the outcomes of action taken and of the key processes involved

Despite all its regulations, pharmacovigilance can only be upheld through the active participation of health professionals. CPME knows that pharmaceutical companies are obliged to present periodic safety reports, and maintain on-going safety information on drugs under investigation. However, follow-up on the safety of marketed drugs is the responsibility of health professionals.
Therefore it is important that the pharmacovigilance structure should be further strengthened with regard to notifications posted by health professionals; measures should be incorporated in order to integrate the health professionals in the system (they should get even more and easier access to all pharmacovigilance data reported to and all safety data documented); appropriate information and training measures should be provided; health professionals should be involved in decision-making, notifications should be optimized through the use of major technical advances, there should be increased participation of associations: professional associations, scientific societies, investigation teams, universities, and, in short, there should be more support of pharmacovigilance initiatives in order to reduce the under notification that is observed at present.
Finally, experts of any kind in the field of drug safety have to publicly reveal their connections to the pharmaceutical industry and other conflicts of interest.

<u>Conclusion</u>
CPME appreciates the attempt of the Commission to strengthen an EU-wide pharmacovigilance system. It acknowledges that the strengthening of the role of EMEA is a logical conclusion of the construction of this supranational authority. We therefore support the Commission in building up a scientific advisory committee within EMEA (Pharmacovigilance Risk Assessment Advisory Committee). The role of industry and patients is well reflected however we believe that the role of physicians as the main source of information within any pharmacovigilance system has to be more emphasized. This could be done through formal incorporation of the supranational bodies of the medical profession. CPME would be willing to take over this task and responsibility.

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