CPME/AD/consultation/210108/004/EN

CPME adopted, on 21 January 2008, the following document "CPME reply to Public Consultation on Legislative proposals regarding a *Strategy to better protect public health by strengthening and rationalizing EU Pharmacovigilance* " (CPME 2008/004EN)

CPME reply to Public Consultation on Legislative proposals regarding a *Strategy to better protect public health by strengthening and rationalizing EU Pharmacovigilance*

CPME previously reacted to the Public Consultation of May 2006: Suggestions to improve and strengthen the Community pharmacovigilance system (CPME 2006/133 Final).

In our reply to the Commission we suggested:

- The setting up of 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 pharmaco-epidemiology, pharmaco-economics 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 for national associations as well as academia, where Pharmacovigilance should become a mandatory subject as a part of teaching clinical and experimental pharmacology

The present Consultation of the Commission aims at pinpointing concrete propositions to change the legal system of the Community in order to improve EU-wide pharmacovigilance. We agree with the Commission that pharmacovigilance is a key public health function, which comprises:

- 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

CPME is the Community Representative of all members of the medical profession.

We are not therefore competent to discuss the wording of individual legal changes as proposed by the Commission. We will however put them into the scope of changes that we proposed in our statement CPME 2006/133 Final.

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 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 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 optimised through the use of major technical advances, there should be increased participation of associations: professional associations, scientific societies, investigation teams, and universities. 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.

With regard to this conclusion of our opinion on a functioning pharmacovigilance system, we answer to the key propositions of the present consultation document:

3.2.1. Fast and robust EU-decision-making on safety issues by rationalizing the existing EU referral procedures and reinforcing the committee structure

CPME agrees to the establishment of a committee within EMEA with clear responsibility for coordinating pharmacovigilance and for making recommendations on the safety of medicines.

CPME agrees to the attempt to rationalize the referral procedures for nationally authorized products: to ensure effectiveness there must be clear obligatory triggers (important safety concerns, withdrawal of products, restrictions to indications and new contraindications). There is a need for lighter procedures and more effective public hearings. The output of referrals must be binding Commissions decisions to ensure that safety actions are taken by all national authorities in all Member States in order to ensure the safety of all European patients.

3.2.2. Clarify / Codify roles and responsibilities and codify standards for industry and regulators.

In the complex field of pharmacovigilance a clarification of the role of EMEA, the Commission and National Authorities is necessary. CPME therefore approves the concept of setting up a concept of “Good Vigilance Practices” (GVP). CPME is however a little cautious on the establishment of a legal basis to adopt regulation on GVP via comitology. We are thoroughly convinced that measures of pharmacovigilance can only be successful when physicians and other health professionals are integrated into the system. This important fact has to be considered when the legal basis for regulation of pharmacovigilance is constructed. Pharmacovigilance is not a bureaucratic or administrative procedure. It is rather a system of information, transparency and reaction.

The information input into any pharmacovigilance system is almost entirely handled by physicians and other health care professionals together with patients; transparency is a combined effort of the health professions and industry under the supervision of regulating bodies; reaction however has to be competent and fast. As the withdrawal of a medicinal product or drug or the restrictions on indications result in severe economic changes for industry and producers a consequent, fast reacting and competent body has to be installed. CPME is convinced that this task can be fulfilled by EMEA together with the NCA network.

3.2.3. – 3.2.5. Obligations of industry

CPME sees that the proposed set of changes is a relevant mix of improvements to the bureaucratic process of industries pharmacovigilance systems, their risk management and their post-authorisation safety studies system.

3.2.6. and 3.2.7. Simplify and make proportional reporting of single serious adverse drug reaction (ADR) case reports and periodic safety update reports (PSUR)

CPME appreciates the changes proposed. Simplifying and rationalizing the process of reactions to ADR reports is an important prerequisite to the rational and fast functioning of any pharmacovigilance system. Setting up a database within EMEA is an important attempt to reduce redundancies.

3.2.8. Strengthen medicines safety transparency and communication

CPME agrees that the present system of the setting up of transparency and communication rules partly in law and partly in guidelines incorporates the risk of incoherence. It is therefore useful to create a legal basis for EMEA to build up a portal on the safety of medicines. This should be a tool to coordinate the communication to and between the Member States.

3.2.9. Clearer safety warnings in product information to improve the safe use of medicines

CPME strongly emphasizes the need for clearer safety warnings in product information. This must be understandable and must rationally name risks and key safety information. Product information should not be a deterrent to the user of medicines but should be assisting physicians and other health care personal to rationally inform patients on possible adverse reactions and risks of a drug.

Conclusion:

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. The role of industry and patients is well respected; 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.