COMITÉ PERMANENT DES MÉDECINS EUROPÉENS
STANDING COMMITTEE OF EUROPEAN DOCTORS

CPME/AD/Brd/271006/133/EN

At its Board meeting in Luxembourg on 27 October 2006, the CPME adopted the following resolution: **Suggestions to improve and strengthen the Community Pharmacovigilance system** (referring to CPME 2006/133 EN/FR)

Suggestions to improve and strengthen the Community pharmacovigilance system

The pharmacovigilance system has become a shared public health activity for the European Community as a whole. The system has managed to detect major problems related to the use of drugs, despite some faults in the system.

In order to improve the system, the following needs should be met: more resources to manage the system appropriately, more supervision of marketing authorisation holders, internal audits and quality controls on the system, faster analysis and decision-making, and mechanisms to assess the impact of decisions made.

Health professionals, patients and stakeholders should be encouraged to notify suspected adverse reactions, thus preventing under notification, and supporting system sustainability.

Drug use studies, quality studies, and the introduction of sensitive indicators are tools that should strengthen and develop drug safety.

Other data sources should also be incorporated, fundamentally based on epidemiological designed studies and further methodologies should be introduced, apart from the suspected adverse reaction notification method. Principally, such methodologies should include intensive monitoring of events associated with drug prescribing.

Any information about drug risks should be communicated to physicians in a way, they can understand and apply in their routine practice. When a measure is taken to improve drug safety, health professionals' change in attitude should be assessed and monitored.

A programme should be drawn up to detect and collect any adverse reactions noted in abnormal laboratory data, particularly with reference to haematological changes, and renal and liver function biochemistry parameters.

The current pharmacovigilance situation, albeit decentralised, employs a structure that is too rigid for health professionals. The latter generally view the

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system as a far removed structure that does not encourage professionals to contribute to the system. CPME therefore proposes to consider setting up local initiatives that work on the daily involvement of the different health professionals.

One initiative that CPME wishes to put forward is the creation of pharmacovigilance committees in the primary health care setting, and also encouraging the work of hospital pharmacovigilance committees, eventually attaining coordination between the two. All health professional should be involved, especially doctors, pharmacists and nurses.

CPME therefore suggests

- ★ 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.

Conclusion

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, 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.

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