"Pharmacovigilance and Public Health: The Stakeholders and their contribution to the safe use of medicines"

PRESS RELEASE

Based on the definition given by World Health Organization, Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse events caused by medicines. The main principle is derived by the Hippocratic dictum "ωφελείν ή μη βλάπτειν" (English translation "to benefit or to not harm") and its main goal is to ensure and promote public health through the continuous monitoring of the safety data of all medicines that are marketed or under clinical investigation, ensuring the patient's right for safe, qualitative and effective medicines.

Health Professionals have the obligation to report to National Organization for Medicines (EOF) all adverse drug reactions that are becoming aware of, by completing the "yellow card".

In practice, information on the occurrence of adverse drug reactions originates either from Health Professionals (physicians, dentists, pharmacists, nurses) or from patients themselves and is reported to National Organization for Medicines (EOF) and/or to those Pharmaceutical Companies which are Marketing Authorization Holders of the concerned medicines.

The reporting of adverse drug reactions contributes to the enrichment of our knowledge towards medicines so that we can take appropriate measures for a more accurate and safe use. By continuous surveillance of the medicines benefit / risk ratio, the benefit of the patients is ensured.

On the occasion of the 4th Annual Congress for the Management of Economics and Health Policy, the Hellenic Association of Pharmaceutical Companies (ΣfEE), is organizing a round table with subject «Pharmacovigilance and Public Health: the stakeholders and their contribution to the safe use of medicines", where the following topics will be presented:

- The regulatory framework and EOF's role
- Clinical Practice and experience
- Prescription practice and adverse drug reactions reporting
- Awareness and continuous update of Health Professional regarding Pharmacovigilance activities by ΣfEE.

With the undivided support of Academicians, the contribution of eminent delegates from Regulatory Authorities and Hospital's area, we aim at the collaboration and co-responsibility of all relevant Parties (Regulatory Authorities, Health Professionals, patients and all pharmaceutical companies-members of ΣfEE).

Having a global and shared responsibility attitude towards Pharmacovigilance, our goal is to highlight the importance the Safety of the medicinal products should hold, for ensuring the highest quality Health services for the Greek citizen.

On the occasion of the round table's organization, ΣfEE published the Pharmacovigilance Manual which will be distributed to Health Professionals and uploaded to ΣfEE website. This manual outlines ΣfEE's position that Drug Safety is a responsibility of all stakeholders.

Dr Barbara Baroutsou

Round Table ΣfEE

"Pharmacovigilance and Public Health: The Stakeholders and their Contribution to the Safe Use of Medicines"

On December 3, 2008 in the context of the 4th Panhellenic Congress on Health Management, Economics and Policies, the Hellenic Association of Pharmaceutical Companies (ΣfEE) held a round table discussion on "Pharmacovigilance and Public Health: The stakeholders and their Contribution to the Safe Use of Medicines", attended by 150 officials.

ΣfEE aims to raise awareness and foster the cooperation of all stakeholders in Pharmacovigilance, keeping with its ethical, scientific, social and legal duty to safeguard public health.

The following speakers participated in the round table discussion:

1) The executives of the National Organization for Medicines, **Ms. G. Terzi** (Head of the Adverse Drug Reactions Department) and **Mr. L. Klironomos,** officer of the ADR Department,
2) Dr. **M. Theodorakis**/Internal Medicine Lecturer of the Therapeutic Clinic of the University of Athens Clinic and Vice-Chairman of the National Pharmacovigilance Committee,
3) Ms. **B. Tsiantou**/Health Economist and Researcher in the National School of Public Health,
4) Ms. **E. Giannoula**/Pharmacovigilance Manager (Roche Hellas S.A.), representing the Pharmacovigilance Group of the Hellenic Association of Pharmaceutical Companies.

The round table discussion was moderated by the undersigned Dr. B. Baroutsou/Internist - Medical Director Sanofi Aventis, Head of the Pharmacovigilance Group of ΣfEE.

Speakers acknowledged the joint responsibility of all the parties involved (health and regulatory authorities and pharmaceutical companies - Marketing authorisation holders and sponsors of clinical trials) share in monitoring the safety of the marketed medicines as well as of those under research.

The participants unanimously agreed on:

- Raising awareness, training and motivating health professionals to use the yellow card and familiarize themselves for reporting ADR's,
- The emphasis that should be placed on correct prescription practices, in order to eliminate adverse reactions,
- the need to contain resources of the health system.

According to the study conducted by the National School of Public Health, presented during the round table discussion, it has been recorded that only 40% of health professionals fills in and submits a yellow card to the National Organization for Medicines, when faced with an adverse reaction.

Adverse events are the 5th most common cause of admissions in the E.U., while it has been estimated that the direct cost from prolongation of hospitalisations per person due to an Adverse Event amounts to approximately to 2,800 euros.

On the occasion of the round table, ΣfEE made public and distributed to delegates:

1) its position on the safe use of medicines,
2) the Pharmacovigilance Manual, compiled by the editorial subgroup of the Pharmacovigilance Group of ΣfEE,
3) the Association's poster and
4) a press release.

All this material has been posted on the Association's website. At the same time, the manual and the Association's poster will be mailed to all health professionals in 2009.

The Hellenic Association of Pharmaceutical Companies has systematically and greatly contributed in raising awareness and providing continuous education on Pharmacovigilance issues to health care professionals, by means of:

- Its close cooperation with the National Organization for Medicines,
- The development of a special glossary and poster on Pharmacovigilance,
- Designing research, collecting and processing statistical data, and
- Organizing or participating in lectures in hospitals, congresses or meetings.

The positive reception of this scientific initiative of the Association encourages the undertaking of joint actions by the Pharmacovigilance stakeholders during 2009.

We address our warmest thanks to the Congress Organizing Committee, the speakers, the members of the Pharmacovigilance working party and the Association's executives, for contributing in the success of the round table.

The position of ΣfEE

on the Safe Use of Medicines

Pharmacovigilance is the science and the activities relating to detection, assessment, understanding and prevention of adverse drug reactions.

As adverse drug reaction is defined any untoward medical event which occurs in a patient after the administration of a medicinal product.

Other special issues which must be recorded and reported in order to improve the safety profile of the drugs are:

- Any information regarding a pregnant woman taking a medicinal product. The Drug exposure in Utero during pregnancy should be reported even if it is not developed any adverse event
- Lack of efficacy cases (it occurs when the drug used have different action from the expected action described in the Summary of Product Characteristics)
- Drug interaction cases (Adverse drug reaction (ADR) derived from the interaction between two or more medicinal products)
- Drug abuse/misuse/overdose cases

All adverse drug reactions, serious and non-serious, derived spontaneously or from clinical studies, **are important** and are described in the section concerning the ADRs in the Summary of Product Characteristics and in Patient's Information Leaflet. After the drug marketing authorisation, the safety data continues to be collected and recorded into the product Periodic Safety Update Report. The Marketing Authorisation Holders, through this document, notify the Competent Authorities about ALL the safety information coming to their attention from the product worldwide experience.

Drugs can be more safe and effective thanks to the attempt and collaboration of all the participants of the Public Health, which are:

Healthcare Professionals (physicians, pharmacist, dentists, nurses): Through the daily practice and/or drug research (pre-marketing and post-marketing studies), healthcare professionals can significantly contributed to the correct and safe use of drugs following the approved drug instructions, be compliant with the clinical trial protocol (for the physician involved in clinical studies), monitoring adequately patients through the daily clinical practice and reporting all the suspected adverse drug reactions arising from the drug use.

A suspected adverse drug reaction can be reported to:

- The local Health Authorities (National Organisation for Medicines, EOF), through the **YELLOW CARD** (http://eof3.eof.gr/web/guest/yellowgeneral)
- The Marketing Authorisation Holder responsible for the medicinal product or the sponsor of a clinical study, if the adverse drug reaction concerns an investigational medicinal product.

Health Authorities (National Organisation for Medicines - EOF, European Medicines Agency - EMEA): They are responsible to implement the legal framework/regulations regarding pharmacovigilance and monitor the compliance of the Marketing Authorisation Holders with European Guidelines and legislation regarding Pharmacovigilance.

They actively follow and evaluate the reporting of adverse drug reactions in order to ensure the correct and safe use of medicinal products.

They continuously evaluate the ratio risk - benefit of medicinal products and maintain the marketing authorisation for the drugs with more benefits than risks.

The Marketing Authorisation Holders must maintain:

- A Pharmacovigilance System for the collection, evaluation, and reporting of safety data to Regulatory Authorities for the products under their responsibility.
- A Risk Management System for the detection, designation, prevention or minimization of the risks related to the use of medicinal products and the appraisal of the effectiveness of these interventions. The Competent Authorities must approve and monitor the Risk Management System.

The procedure of expedited and/or periodic reporting of adverse drug reactions to the Competent Authorities is accomplished within strict submission timelines in order to monitor systematically and promptly the drug safety data and to prevent immediately possible risks either in pre-marketing either in post-marketing period.

Consumers (patients, friends or patients' relatives). They can report possible adverse drug reactions to Healthcare Professionals and/or Competent Authorities and /or Marketing Authorisation Holders.

The patient's safety and wellbeing must be a priority for all participants in the sector of Health. The Hellenic Association of Pharmaceutical Companies supporting the culture and enhancement of continuing Pharmacovigilance training, with the assistance of specialised scientists (representatives of companies participating in ΣfEE), collaborates with the Authorities, healthcare professionals and investigators in order to emphasize the importance of safety for medicinal products in a health system with high level services to the citizens.

Yellow card to EOF. Red card to risk!

The Safety of Medicines is everyone's Responsibility

The safety of medicines is our fundamental concern. With respect to our ethical and legal obligations, we align with the Health Authorities and encourage Health Care Professionals to complete the special, confidential form of EOF, the "Yellow Card". We strive for safer medicines and support every effort undertaken by the competent authorities and the scientific community for the promotion of public h ealth.

Help make medicines safer. Complete the "Yellow Card".
Report:

- **ALL** Adverse Events for New Medicines [N] (marketed up to one year)
- **SERIOUS** adverse events for Known medicines (marketed more than one year)

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