ΣΥΝΔΕΣΜΟΣ ΦΑΡΜΑΚΕΥΤΙΚΩΝ ΕΠΙΧΕΙΡΗΣΕΩΝ ΕΛΛΑΔΟΣ — SFEE — HELLENIC ASSOCIATION OF PHARMACEUTICAL COMPANIES

Athens, December 1, 2008

PRESS RELEASE

«Pharmacovigilance and Public Health:
The Stakeholders and their contribution to the safe use of medicines»
December 3, 2008

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 the National Organization for Medicines (EOF) all adverse drug reactions that they become 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 the 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 (SFEE), is organizing a round table with the 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 reaction reporting**
- **Awareness and continuous update of Health Professional regarding Pharmacovigilance activities by SFEE.**

With the undivided support of Academicians, the contribution of eminent delegates from Regulatory Authorities and Hospitals, we aim at the collaboration and co-responsibility of all relevant parties (Regulatory Authorities, Health Professionals, patients and all pharmaceutical companies-members of SFEE).

Having a global and shared responsibility attitude toward 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, SFEE published a Pharmacovigilance Manual that will be distributed to Health Professionals and uploaded to the SFEE website. This Manual outlines SFEE's position that drug safety is a responsibility of all stakeholders.

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