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## Pharmacovigilance Committee of Greek hospitals

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The pharmacovigilance system in Greece is a checking mechanism for the efficacy of all medical products in addition to the observed adverse effects (AEs) during their use, while at the same time serving as an evaluation system for possible misuse and a source of important scientific information for better clinical practice. Critical to the success of this system is the effective and persistent participation of healthcare professionals, among them of which the hospital pharmacist has an obvious leading and connecting role.

### Composition of the Pharmacovigilance Committee

Each hospital is obligated by law to establish a Pharmacovigilance Committee (PC) which sends reports directly to the National Organization for Medicines (EOF). The members of the PC are appointed by the Board of Administration of the hospital, after a recommendation of the Scientific Committee. Members of the PC are usually three physicians (preferably one of them is a clinical pharmacologist) and the fourth member is the head pharmacist of the Pharmacy Department. If the head pharmacist is also a member of the SC then automatically becomes president of the PC law restricts participation of nurses in PC although they have the closest contact with patients.

### Role of the PC

1. To remind and constantly encourage all healthcare professionals (doctors, pharmacists, nurses, technicians) to immediately report to the PC all the AEs regarding drugs, medical devices or other medicinal products that they handle during their practice in the hospital, even if they have doubts about the correlation between the AEs and the suspected product.
2. To set the procedure for checking that

all the AEs are reported and collecting the appropriate reporting cards on a periodic basis.

3. To evaluate and forward the reports to EOF. These are contained in three types of colour-coded reporting cards (**Yellow Card** for medicines, **White Card** for medical devices and medicinal product, **Confidential Report Form for the Pharmacist**, regarding qualitative issues for all EOF competence products).
4. To organise educational lessons for all health staff regarding critical pharmacovigilance issues.

The PC meetings should be held regularly (at least twice a year) and the results of each session should be communicated to all scientific personnel in the hospital and EOF, if necessary. An additional duty of the PC is to ensure that all medical departments of the hospital are supplied with an efficient number of reporting cards.

### Pharmacovigilance data and the role of the hospital pharmacist

The annual data from the National Basis for Pharmacovigilance in EOF show only 8,850 reports by healthcare professionals and pharmaceutical companies cumulative for years 2001 (794 reports) to 2007 (1,591 reports). Though the number of reports is increasing every year, it still reveals low participation of healthcare professionals in the pharmacovigilance system.

This is the main reason that the role of the hospital pharmacist is usually restricted in mediating between EOF and clinical departments of the hospital when problematic batches of products need to be analysed in central laboratories of EOF. Hospital pharmacists are also responsible for ensuring that all official notifications by EOF relating to the safety of drugs and other medical products and all reports by

the pharmaceutical companies are forwarded to health staff in a timely manner. Simultaneously, the primary duty of the pharmacist is to collect any available stock of problematic batches and return them to the supplier according to official directions, replacing it – if possible – with a new, safe batch.

The responsible pharmacist may also provide prescribers the valuable updated information via the National Basis for Pharmacovigilance, showing the possible drug safety risks. When it is necessary, pharmacists can be the one to inform the patient (mostly outpatients). Finally, an important involvement of hospital pharmacists may occur in cases of use of ‘orphan’ drugs, e.g. lenalidomide, thalidomide, bosentan, as this special category of drugs is distributed only through hospital pharmacies of the National Health System and is supervised for pharmacovigilance by EOF very strictly. That is why the pharmacist should get certificated education prior to any involvement (it is an obligation of the supplier to EOF to educate the pharmacists as well as the involved clinical physicians).

Finally, in the period of novel influenza A (H1N1) pandemic, hospital pharmacists in Greece face the significant challenge and the EOF directives to guarantee the readiness of the PC in order to respond to the growing demands for the collection of reports on AEs regarding new flu vaccines and antiviral drugs.

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