AZIENDA OSPEDALIERO - UNIVERSITARIA di CAGLIARI

Sezione di:
FARMACOLOGIA CLINICA
P.O. San Giovanni di Dio – Via Ospedale, 46 - 09124 Cagliari - Tel. 070 6092320 - Fax 070 653584

Responsabile: Prof. Maria Del Zompo

- CENTRO PER LO STUDIO E LA TERAPIA DELLE CEFALEE PRIMARIE "FRANCO TOCCO"
- CENTRO DI PSICOFARMACOLOGIA CLINICA
- CENTRO PER LO STUDIO E LA TERAPIA DEL MORBO DI PARKINSON
- SERVIZIO INFORMAZIONE SUL FARMACO

Università di Cagliari
Dipartimento di Neuroscienze
BERNARD B. BRODIE

http://fc.unica.it/
www.centrocefalee.it
http://www.farmaci-fc.it/

31 January, 2008

Comment on the consultation on the review of pharmacovigilance regulation in EU

It is widely accepted as definition of Adverse Drug Reaction (ADR) the following: "a response to a drug that is noxious and unintended and occurs at doses normally used in men for the prophylaxis, diagnosis or therapy of disease, or modification of physiological function".
Moreover, pharmacovigilance includes the promotion of the safe use of drugs and the creation of appropriate structures and means of communication needed to perform its tasks.
In Europe, all efforts are focused almost exclusively on the identification and classification of ADRs.

To this regard, we would like to draw the attention on the following issues:

ADR definition

We reckon the definition of ADR should include the name of the suspected disease or symptom or syndrome.

Differential diagnosis

An ADR should be considered as a suspected disease and therefore be included in the diagnostic evaluation made by the physician. In fact, we consider very important to avoid that a symptom may be considered as a disease when it is input in a data base (i.e. hyperuricaemia considered as gout).

ADR evaluation

We believe the signalling is correct even in the case it is made by non-physicians, but we reckon only a physician can evaluate whether that signalling must be considered as an ADR or not, and more precisely a Clinical Pharmacology specialist.
With this procedure the ADR signalling would be much more useful in clinical daily practice and it would have a great and effective impact on the safe use of drugs, avoiding to cause simple fear of using that particular drug or, even worse, to provoke a reduced attention toward the countless ADRs that are listed in all the report forms.
In this case quantity is not a qualitative value, on the contrary it distracts the attention from the real problem, that is the relationship between the single human being and the drug, and the biological basis of the ADR of a particular individual to that particular substance.
This is the main issue on which the European pharmacovigilance should focus its attention.

Maria Del Zompo, MD
Head
Section of Clinical Pharmacology
Department of Neurosciences
University of Cagliari
Italy

Raffaella Ardau. MD
Clinical Pharmacologist
Section of Clinical Pharmacology
Department of Neurosciences
University of Cagliari
Italy