Journal of Pharmacovigilance
ISSN: 2329-6887

Businaro, J Pharmacovigilance 2013, 1:4
DOI: 10.4172/2329-6887.1000e110

Editorial Open Access

Why We Need an Efficient and Careful Pharmacovigilance?

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The main purpose of pharmacovigilance is to evaluate the benefit/risk profile of the pharmacological therapy and to promote a more rational use of medicines in the population. 5% of all hospital admissions in Europe are due to Adverse Drug Reactions (ADRs); ADRs represent the fifth cause of hospital death and about 5% of hospitalized patients incur in an ADR. It has been estimated that ADRs are responsible for 197,000 deaths each year in the European Union and the total social cost of ADRs has been estimated at € 79 billion per year.

Pharmacovigilance aims to protect public health by reducing the impact of ADRs and optimizing the use of drugs: in this connection the European Union has created the European Medicines Agency, EMA, to strengthen the European network of pharmacovigilance, also providing a multimedia archive documents containing periodic safety update reports for medicinal products (PSUR- Periodic Safety Update Report), containing information on the active ingredient. The EMA will draw up a list containing all authorized active substances and all the features related to the PSUR.

One of the main issues concerns the use and appropriateness of drugs in different ages of life, besides the assessment of the safety of drugs, ranging from problems related to lactation to the polytherapies in the elderly. Another aspect of great interest will be to assess the therapeutic advances of new drugs, analyzing the differences in the evaluation criteria between USA and the European Union.

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Received January 03, 2013; **Accepted** January 03, 2013; **Published** January 05, 2013

Citation: Businaro R (2013) Why We Need an Efficient and Careful Pharmacovigilance? J Pharmacovigilance 1: e110. doi:10.4172/2329-6887.1000e110