Current roles of the patients in Pharmacovigilance activities: regulatory perspective.

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In the last years, Regulatory Authorities have focused the attention on the role of patients in the reporting of adverse drug reactions (ADRs). European Medicines Agency has emphasized the role of patients in the Pharmacovigilance system through the new European Pharmacovigilance legislation (Regulation EU No 1235/2010 and Directive 2010/84/EU) [1]. To sensitize the involvement of the patient in the spontaneous reporting system, potential causes of underreporting were investigated and included poor awareness, difficulties with ADR reporting procedures and forms, confusion as to who reports ADRs, lack of feedback on previous ADRs submitted, ADR resolved, and prior negative experience. The main reasons for supporting the involvement of patients in the Pharmacovigilance system consist in the promotion of patients' rights and equity and in the awareness of the benefit that can be provided by the involvement of patients. In fact, patients could provide different information compared to health-care professionals, reporting also ADRs related to the use of over-the-counter medicines, and providing detailed information about the event and its impact on quality of life. In this regards, it is fundamental to receive reports from both healthcare professionals and patients in order to assess the true and complete nature of an ADR. Despite all these advantages, concerns were also arisen about the direct role of patients in the reporting of ADRs. In fact, patient reporting could reduce the quality and obstruct the analysis investigating the cause and effect between a drug and an adverse event, creating an additional 'noise' able to distract the signal detection. Moreover, consumer reports may be more easily influenced by media and thereby to provide more selective reports than healthcare professionals. However, there are no evidence suggesting a negative impact of patient reporting on signal detection. On the contrary, several benefits have been demonstrated in different European countries. Given the new aims recommended by the European legislation, and the important role that patients could cover in a spontaneous reporting system, different activities were performed to promote patient reporting at a national level. In Italy, a Pharmacovigilance active project was performed to promote the ADR reporting by patients through the community of pharmacists. Patients' involvement in the drug therapy and, specifically, in the reporting of ADRs could have a positive addictive value to a Pharmacovigilance system and should be widely accepted to provide further insights on ADRs.

References:

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1. Directive 2010/84/EU of the European Parliament and the Council of 15 December 2010 amending, as regards pharmacovigilance, Directive 2011/83/ EC on the Community code relating to medicinal products for human use. European Parliament and the Council of the European Union 2010. Available from: http://ec.europa.eu/health//sites/health/files/files/eudralex/vol-1/dir_2010_84/dir_2010_84_en.pdf [last accessed on 10 Apriòl].