Delphine Bertram, J Clin Trial 2017, 7:4 (Suppl)
DOI: 10.4172/2167-0870-C1-016

## Adverse drug reaction reporting by patients in 50 countries

**Delphine Bertram**
Xendo B.V., Netherlands

The aim of this work is to review the current patient Adverse Drug Reaction (ADR) reporting system in 50 countries and to analyze its implication on pharmacovigilance system. National Competent Authorities (NCA) is surveyed and a literature review was conducted in fifty countries across five continents. Of the 50 countries included in this study, patient report ADR to NCA in 44 countries (88%) were taken. Twenty-six countries (59%) have created a patient-specific ADR reporting form. Depending on the country, the way to declare an ADR is more or less easy to find from the NCA website but on the average 3 clicks are requested to access the ADR form. The total number of fields to complete per ADR form varies from 6 (Brazil) to 59 (Austria) with a mean of 36 items. Reports from patients represent an average 9% of total ADR reports compared to HCP reports received by NCAs but a fairly large disparity can be observed. Efforts are still to be made in the field of pharmacovigilance to encourage patients to report ADR especially in developing countries. However, the majority of the 50 countries surveyed in this study really began to implement a patient ADR reporting system (16 countries began in 2012 or 2013), which can explain the fact that the patient reporting is fairly low compared to HCP. When NCA implemented an online ADR reporting form, the rate of reporting is increasing. Means to report should be extended for the development of applications in mobile devices enabling faster return at any time. Only few countries have currently implemented a mobile application. Each country should promote ADR reporting system using all means of communication included Internet and social networks.

### Biography

Delphine Bertram, PharmD, PhD, has more than 12 years of experience in managing the safety of clinical trials. She has built and managed the Vigilance Unit of the second Public French Hospital. She has hosted and managed European and French Health Authorities inspections (preparation, conduct and CAPA management), planned and executed Internal/external audits. She has extensive knowledge of the international regulatory (ICH, FDA guidance's, GVP, MEDDEV) environment for both pre- and post-marketing products, e-Health and social media monitoring. She has co-developed a free application to allow patients and healthcare professionals to report drug adverse effect to the health authority. She has a particular interest in e-Health precisely in the use of social data to improve drug surveillance.

delphine.bertram@xendo.com

**Notes:**