OMICS Group Conferences
Accelerating Scientific Discovery

2nd International Conference and Exhibition on
Pharmacovigilance & Clinical Trials
November 18-19, 2013 Hilton San Antonio Airport, TX, USA

Current status & challenges of pharmacovigilance programme of India

Prasad Thota, V. Kalaiselvan and G. N. Singh
National Coordination Centre, India

India's pharmaceutical market was 3rd in volume & 13th in terms of value globally in 2012, at $14 billion. Various factors have contributed to the industry's growth in India, including the country's aging population, changing disease profiles, growing affluence/disposable income, increasing provider penetration, and continued foreign direct investment (FDI) inflow. Despite challenges, the outlook for 2013 is promising, for three reasons: First, there is an inherent demand for health care products and services due to India's large patient base and increasing awareness of wellness by its growing population. Second, both the government and private sectors are increasing their initiatives to improve health/well-being and enhance population coverage (including access to rural and low-tier cities). Third, the government has indicated that it will provide free drugs to the entire non-affording population and has allocated a budget of $5.4 billion for this purpose, a large part of which will go towards the purchase of medicines. In order to promote the safety of these medicines Government of India has initiated a nation-wide Pharmacovigilance programme under the aegis of Ministry of Health & Family Welfare. Indian Pharmacopoeia Commission, Ghaziabad is functioning as National Coordination Centre for Pharmacovigilance Programme since 15th April 2011 in collaboration with WHO Collaborating Centre for International Drug Monitoring, Uppsala Monitoring Centre (UMC). So far 39,523 Individual Case Safety Reports (ICSRs) have been committed to WHO-UMC through a software "Vigiflow" (an ICSR management system developed & hosted by UMC).

Method: We performed a retrospective observational study of the ADRs reported to the National Centre for Pharmacovigilance Programme of India for the period from July 2011 to March 2013. All drugs were classified using the anatomical therapeutic chemical (ATC) classification code system, and subsequently entered into a database. ADRs were considered serious if one of the following criteria were met according to the ICH E2A guidelines: the ADR is life threatening; it led to hospitalization/prolonged stay in hospital; caused congenital malformation; permanent disability; or, medically serious condition. Descriptive statistics and logistic regression using SPSS 14.0 were undertaken.

Results: The results showed that among all the reported ICSRs (n=39,523), 20.4% referred to serious ICSRs (n=8088). The majority of these serious ICSRs (59%) were led to hospitalized by patients, (32.64%) belonging to other medically important serious cases (25.7%), life threatening (7.38%) and, disabled (1.61%) according to ICH E2A guidelines for seriousness. Total 39,523 ICSRs represented 47,393 ADRs of medicines, biological products (including blood-products and vaccines), herbals and traditional medicines in Indian patient's drug safety database i.e. Vigiflow. Out of 39,523-20,158 (51%) were males, 19,010 (48.09%) were females & 16 (0.91%) with unknown gender. Out of 39,523 ICSRs-25,557 (64.66%) were reported by physicians, 7,444 (18.83%) by other healthcare professionals & 5,830 (14.75%) were by pharmacists. Out of 39,523 ICSRs-32,959 (83.39%) represents adults, 1,770 (4.47%) of elders, 1,604 (4.05%) of Infants 1379 (3.49%) of adolescents followed by 1,368 (3.46%) of child ICSRs.12, 145 (25.62%) ADRs fell in to gastrointestinal disorders for the reported 47,393 ADRs according to Vigiflow system organ class by preferred terms.

Conclusion: The major challenges are distinguishing signals from background 'noise', providing the evidence for making regulatory decisions based on strengthened signals, including changes in product information & alerting Indian prescribers, manufacturers and the public to new risks of adverse reactions.

prasad.thota187@gmail.com