Pharmacovigilance: A brief outlook

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Abstract

The drug safety monitoring is now the mandate area of interest for Regulatory Authority; Ethics committee and Pharmaceutical/bio-pharmaceutical companies. Every drug is associated with beneficial as well as undesirable or adverse effect. Nuremberg code 1947 and the thalidomide tragedy of 1960's lead to stringent ethics and regulations. Previously the benefit/risk ratio for drug(s) under study and marketed drug(s) were not transparent to Regulatory Authorities and safety of patient was not on priority. The drug safety issues were globalised, strengthen and systematized after the establishment of 1964 Declaration of Helsinki; World Health Organization (WHO) Programme for International Drug Monitoring in 1968; birth of ICH - International conference on harmonisation 1990 and 1996 - ICH GCP guidelines released. Adverse drug reactions (ADR) are the common clinical problem. The hospitalization due to ADRs in some countries is about 15.1%. In addition, 10-20% of the hospital inpatient suffers from ADRs. Appropriate and effective monitoring of ADRs, i.e. Pharmacovigilance, is the only best way to safeguard the public health. ICSRs originating from solicited and unsolicited categories are submitted to Regulatory Authority in the form of CIOMS and MedWatch 3500A Drug. The ICSRs submission to Regulatory Authority depends on causality relationship with suspect drug and the expectedness. Serious unexpected adverse drug reactions (SUSARs) are expeditable to Regulatory Authority. The spontaneous reporting system (SRS) is the first and most widely used method to report ADRs in spite of under-reporting as a major limitation. Based on those reported cases signal is generated.ADRs which are assessed as special terms are by default considered for signal analysis. The safety monitoring of drug is assessed by benefit/risk ratio analysis by submission of PBRER/ PADER as per Regulatory timelines. The severity of under-reporting of ADRs is considerably high; it estimates that only 8% of ADRs are reported. There are many factors associated with under reporting of ADRs; categorized as personnel and professional characteristics of healthcare professional and their knowledge and attitude to ADR reporting. Under-reporting can be significantly improved by appropriate educational intervention. Pharmacovigilance is an important and integral part of clinical research. Pharmacovigilance is "defined as the pharmacological science relating to the detection, assessment, understanding and prevention of adverse effects, particularly long term and short term adverse effects of medicines. This addresses what exactly is pharmacovigilance? What do we know of its benefits and risks, challenges and the future hold for pharmacovigilance in Indian medicine. Here the main focus on the aims and role of pharmacovigilance in medicines regulation and their Partners. This article describes and discusses the National programme of pharmacovigilance and centre in India. There role in collecting the reports ADRs of medicines. Further effectiveness and risk assessments of therapies are been discussed. The important role played by health care professional, pharmaceutical industries, media, and programmes carried by WHO. Finally the conclusion describes the major challenges and achievements for the future pharmacovigilance programme. Pharmacovigilance is not new to India and has infact been going on from 19982. When India decided to join the uppasla centre for adverse event monitoring. The importance of pharmacovigilance is withdrawls the regulatory agencies, media; consumers have become more aware about the benefit and risks of medicines. "An adverse event is defined as any un toward medical occurrence that may present during treatment with a drug but which does not necessarily have a relationship with its use." "An adverse drug reaction is any noxious, unintended and undesired effect of a drug, which occurs at a dose used in human for prophylaxis, diagnosis, therapy or modification of physiological function." Spontaneous reporting of adverse drug reaction and adverse events is an important tool for gathering the safety information for early detection. In recent years many Indian companies are increasing the investment in research and development and are enhancing their capacity to develop and market new drugs with their own research efforts. Further India is becoming a hub for clinical research activities due to its large population, high enrolment rate and low cost 3. Moreover, the lag period when a drug is placed for the first time on the market in USA, Europe, and Japan or somewhere in the world and its subsequent availability in India has decreased considerably. As a result, for such drugs the long term safety data is not available and the time of their marketing in India. This is clear by the fact that all the high profile drugs that have been recently withdrawn were available in Indian market. In such cases, the Indian regulatory agencies cannot count on the experience of other market to assess benefit risk balance of a drug. There by stressing the importance of developing their own adequately designed pharmacovigilance system in India. For an effective pharmacovigilance system to be functional and efficient, all the stake holders need to be alert and attentive throughout the life cycle of a medicinal product in the market .The office of the Drugs Controller General of India(DCGI) has been making sincere attempts for the implementation the National Pharmacovigilance programme (NPP) in India. To full fill the pharmacovigilance obligations for its marketed products, as per regulations, a generic company in India is mainly to carry out the following activities. Collection monitoring, and reporting of spontaneous

adverse reactions, including expedited reporting of serious unexpected adverse reactions and preparations. Pharmacovigilance help to prevent adverse drug effects: Medical science has grown in leaps and bounds since the days of Hippocrates. Modern day pharmaceutical drugs are really life saves. They have increased life expectancy and improved the quality of life for millions of people. But there is the other side of the coin as well; these drugs sometimes have very adverse effects that can even be life threating.

Biography:

Manoj Gopala has completed his masters in pharmacy at the age of 26 years from Jawaharlal Nehru Technological University, India and certified professional in clinical research and management, Klinexa life sciences, Aubrey, Texas, USA. He is the team leader in iSafety Systems, a premier Pharmacovigilance and clinical service organization, Hyderabad, India. He was professional instructor in pharmacovigilance and clinical research and one of board member in Telangana National Forum for pharmacy students.