Pharmaceutics & Drug Innovation E-Science Information
Pharmaceutics and Drug Innovation
Volume 2 & Issue 1
Editorial

The Importance of Pharmacovigilance

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Received: March 07, 2024; **Accepted**: April 05, 2024; **Published**: April 12, 2024

Editorial

Medicines are chemical substances that react to external stimuli (microbial agents, moisture, heat, light), and in many cases such reactions can lead to physical changes that result in decreased effectiveness or potency and side effects. Therefore, detecting, recording and reporting adverse reactions (ADRs) has become vital in the safe use of medicines. ADRs often result in temporary or permanent injury, disability, or death, sometimes requiring discontinuation of drug therapy, change of therapeutic agent, or change in dosage. Often the occurrence of ADRs can lead to the patient being admitted to a hospital, or even prolong a stay in a health care facility [1]. All medicines can cause ADRs, but not all patients develop the same type and level of side effects. To this end, the concept of pharmacovigilance has been introduced with the main objective of increasing safety and maximizing therapeutic outcomes. The effectiveness of the post-marketing surveillance programme is directly dependent on the active participation of healthcare professionals as they are in the best position to report a suspected drug ADR [2,3]. During the drug development phase, information is obtained regarding the therapeutic activity of a drug, but less about its safety because clinical trials are conducted in a controlled environment in a limited number of patients and have a specific duration. Once authorized, they are used on a large scale by thousands of patients belonging to different age groups. Only in the post-marketing phase, unusual and rare ADRs can be detected. In addition, different medicines can interact with each other causing what is known as drug-drug interactions. To some extent, medicines can also interact with food, leading to the same undesirable effects. These interactions can occur at any stage of the drug's presence in the body, including pharmacokinetic processes such as absorption, distribution, metabolism and excretion, and could either reduce or increase the effect of other drugs, or produce a different, new effect and ADRs.

These issues cannot be decided during pre-marketing clinical trials. Drug safety issues should be of increasing concern as the population grows and diversifies taking into account the accelerated ageing, drugs are increasingly widely used and patients often resort to polypharmacy. At the same time, changes in access to all medicines and information about them, the growing consumption of medicines, the explosion of open trade and the increasing use of the internet over the last decade have led to the realization that the scope of pharmacovigilance should be extended beyond the strict limits of detecting new signals or safety concerns. 2 However, risks from medicines could be minimized by educating the patient about drug safety and by maintaining a good collaboration within the medical team: doctor or pharmacy. The most widely used method to generate pharmacovigilance signals and identify new safety issues, with recognized benefits, is spontaneous reporting of ADRs. These systems operate in most developed countries and many developing countries and are usually administered by a central or regional agency. They collect reports from both physicians and other healthcare professionals, such as pharmacists and nurses, and non-healthcare professionals (patients or caregivers), either directly or through reporting to pharmaceutical companies [4]. Therefore all types of suspected drug ADRs should be reported, whether known or unknown, serious or less serious, frequent or rare, and regardless of their causal relationship.

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