Research & Reviews in Pharmacy and Pharmaceutical Sciences e-ISSN:2320-1215

Impact of Pharmacovigilance Activities

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Perspective

Received: 03-Jan-2022, Manuscript No. JPPS- 22-52066; **Editor assigned:** 05-Jan-2022, PreQC No. JPPS- 22-52066 (PQ); **Reviewed:** 17-Jan -2022, QC No JPPS- 22-52066; **Revised:** 20-Jan-2022, Manuscript No. JPPS-22-52066(R); **Published:** 27-Jan-2022, DOI: 10.4172/ 2320-0189.11.1.001

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DESCRIPTION

The pharmacological science linked to the collection, detection, assessment, monitoring, and avoidance of adverse effects with pharmaceutical goods is known as Pharmacovigilance (PV, or PhV). The words "pharmacovigilance" come from the Greek words pharmakon (drug) and vigilare (vigilance) (Latin for to keep watch). As a result, pharmacovigilance is largely focused on Adverse Drug Reactions (ADR), which are defined as any unpleasant and undesired response to a medicine, such as lack of efficacy. (With the most recent revision to the applicable legislation, the caveat that this term only applies to doses ordinarily used for disease prophylaxis, diagnosis, or therapy, or for the alteration of physiological disorder function, was removed.) Medication errors, such as overdosing, drug misuse and abuse, and drug exposure during pregnancy and lactation, are also of importance, even if no adverse event occurs, because they may result in an adverse medication reaction.

Information obtained from patients and healthcare providers through pharmacovigilance agreements, as well as data obtained from other sources such as the medical literature, is crucial in supplying the data required for pharmacovigilance. In most countries, adverse event data acquired by the licence holder (typically a pharmaceutical corporation) must be submitted to the local drug regulatory body in order to market or test a pharmaceutical product.

In the end, pharmacovigilance is concerned with detecting the risks connected with pharmaceutical products and reducing the chance of any harm to patients. To assess their compliance with global laws, regulations, and advice, companies must execute a complete drug safety and pharmacovigilance audit.

The most prevalent activity related with Pharmacovigilance (PV) is adverse event reporting, which consumes a large amount of resources for drug regulatory authorities (or equivalent government organisations) and drug safety departments in pharmaceutical corporations. Receiving, triaging, data entry, appraisal, distribution, reporting (if appropriate), and archiving of Adverse Event (AE) data and documentation are all part of the AE reporting process. AE reports can come from a variety of places, including: spontaneous reports from healthcare professionals or patients (or other intermediaries); solicited reports from patient support programmes; reports from clinical or post-marketing studies; reports from literature sources; reports from the media (including social media and websites); and reports submitted directly to drug regulatory authorities.

In most countries, AE reporting is a legal requirement for pharmaceutical companies. AE reporting also gives information to these firms and drug regulatory agencies, which are crucial in determining a medicine's risk-benefit balance. The decision of what constitutes an individual case safety report is one of the core concepts of adverse event reporting. It's critical to evaluate whether the "four elements" of a valid individual case safety report are present during the triage phase of a possible adverse event report: (1) an identifiable patient, (2) an identifiable reporter, (3) a suspicious drug, and (4) an adverse event.

The case is not a valid individual case safety report if one or more of these four items are missing. Although there are no exceptions to this rule, there may be times when a judgement call is necessary. The phrase "identified," for example, isn't always apparent. Even if a physician reports that he or she has a patient X who is taking medicine Y and has had Z (an adverse event), the report is still legitimate because the patient is not specifically identified. This is because the reporter has knowledge on the patient and can be identified (as a genuine person) by the doctor.

The other three aspects are similarly subject to the concept of identifiability. Although unusual, it is not unheard of for an anonymous individual (or on behalf of an anonymous patient, disgruntled employee, or former employee) to report bogus adverse event "cases" to a corporation in order to harm the company's reputation or product. The source of the report should be determined in these and all other cases (if possible). The medicine must also be named specifically in general. Drugs are sold under many trade names in different countries and regions of the world.

Furthermore, there are several generics that could be confused for the trade product. Finally, there's the issue of counterfeit medications causing negative side effects. If at all feasible, try to collect the sample that caused the adverse event and send it to the European Medicines Organization, the Food and Drug Administration, or any government agency that investigates AE reports.

This would not be a valid case if the reporter couldn't remember the name of the drug they were taking when they had an adverse event. This idea also applies to unfavourable circumstances. If a patient reports that they had "symptoms" but cannot be more specific, the report may be technically valid, but it will be of little use to the company's pharmacovigilance department or drug regulatory authorities.