

## A Brief Note on Drug Safety Surveillance

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Pharmacovigilance is like a sunshade to describe the processes for monitoring and evaluating ADRs and it is a key component of effective drug regulation systems, clinical practice and public health programmes. The number of Adverse Drug Reactions (ADRs) reported resulted in an increase in the volume of data handled, and to understand the pharmacovigilance, a high level of expertise is required to rapidly detect drug risks as well as to defend the product against an inappropriate removal. This would consider litigious and important drug safety issues that have the potential to affect public health adversely beyond national boundaries. Recently, pharmacovigilance has been confined, mainly to detect adverse drug events that were previously either unknown or poorly understood. Today many pharmacovigilance centers are working for drug safety monitoring in this global pitch, however, at the turn of the millennium pharmacovigilance faces major challenges in aspect of better safety and monitoring of drugs [1].

Drug safety and pharmacovigilance remains a dynamic clinical and scientific discipline. Pharmacovigilance is defined as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem it plays a vital role in ensuring that doctors, together with the patient, have enough information to make a decision when it comes to choosing a drug for treatment [2]. However, despite all their benefits, evidence continues to get those bigger adverse reactions to medicines which are common, yet often preventable, cause of illness, disability and even death. In order to prevent or to reduce harm to patients and thus improve public health, mechanisms for evaluating and monitoring the safety of medicines in clinical use are vital.

Some key points for future consideration which may be improved to make better pharmacovigilance practice:

- Pharmacovigilance should be less focused on finding harm and more on extending knowledge of safety.
- Complex risk-benefit decisions are amenable to, and likely to be improved by, the use of formal decision analysis.
- Pharmacovigilance should operate in a culture of scientific development. This requires the right balance of inputs from various disciplines, a stronger academic base, and greater availability of basic training, and resource which is dedicated to scientific strategy [3].

**Globalization:** The globalization of drug distribution and the increased exposure of massive populations to large volumes of medicines. These include novel chemical entities used for symptomatic relief and lifestyle modification as well as medicines used in developing countries to curb the prevalence of pandemic diseases such as HIV/AIDS, malaria and tuberculosis.

**Broader safety concerns:** The scope of pharmacovigilance continues to broaden as the array of medicinal products grows [4]. There is a realization that drug safety is more than the monitoring, detection and assessment of ADRs occurring under clearly defined conditions and within a specific dose range. Problems resulting from irrational drug use, overdoses, polypharmacy and interactions, increasing use of traditional and herbal medicines with other medicines, illegal sale of medicines and drugs of abuse over the Internet increasing self-medication practices substandard medicines, medication errors, lack of efficacy are all within the domain of pharmacovigilance.

**Public health versus pharmaceutical industry economic growth:** There may be shortcomings and at times conflicting interests within the pharmaceutical industry when dealing with public health concerns arising from drug safety issues [5]. The industry needs to overcome weaknesses in safety monitoring during clinical trials and post-marketing surveillance.

**Monitoring of established products:** There is the erroneous belief that generic drugs are inherently safe even when they interact with other medicines. The generic sector is the largest supplier of essential drugs.

**Attitudes and perceptions to benefit and harm:** Healthcare providers, patients and the public have responded in different ways to these changing trends as has been described in previous chapters. The harm caused by medicines has been shown to be significant.

**Outcomes and Impact:** Along with increased public awareness over safety of medicines, there is an increasing public stare on the performance of the health professions, industry and regulators.

### CONCLUSION

Pharmacovigilance continues to play a crucial role in meeting the challenges posed by the ever increasing range and potency of medicines, all of which carry an inevitable and some- times unpredictable potential for harm. When adverse effects and

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Received: July 7, 2021, Accepted: July 21, 2021, Published: July 28, 2021

Citation: Gude MR (2021) A Brief Note on Drug Safety Surveillance. J. Pharamacovigil. 9:326. doi-10.35248/2329-6887.21.9.326.

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toxicity do appear, especially when previously unknown, it is essential that these are reported, analysed and their significance is communicated effectively to the audience having knowledge to interpret the information. For all medicines, there is a trade-off between the benefits and the potential for harm. The harm can be minimized by ensuring that medicines of good quality, safety and efficacy are used rationally, and that the expectations and concerns of the patient are taken into account when therapeutic decisions are made. To achieve this is to serve public health, and to foster a sense of trust among patients in the medicines they use that would extend the confidence in the health service in general, ensure that risks in drug use are anticipated and managed, provide regulators with the necessary information to amend the recommendations on the use of the medicines, improve communication between the health professionals and the public and educate health

professionals to understand the effectiveness or risk of medicines that they prescribe.

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