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Commentary

Brief Note on Pharmacovigilance

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INTRODUCTION

Pharmacovigilance is a broad term for recording, analyzing, monitoring, and preventing side effects of medicines and treatments. This is a completely scientific and process-driven field within the pharmacy. The etymology of the word "pharmacovigilance" is Pharmacon (medicine in Greek) and Vigilale (monitored in Latin). Therefore, pharmacovigilance focuses on side effects (ADRs), which are defined as adverse and unintended reactions to drugs, including lack of efficacy (although this definition is the prevention, diagnosis, or treatment of the disease. Applies only to the doses normally used for) or changing physiological dysfunction was excluded in the last amendment of the current law. Drug overdose, misuse, abuse, and drug exposure during pregnancy and lactation are interesting because they can adversely affect the drug even in the absence of adverse events.

Information received from patients and healthcare providers through pharmacovigilance agreements, as well as other sources such as the medical literature, play an important role in providing the data needed to carry out pharmacovigilance. To sell or test a drug in most countries, adverse event data received from marketing authorization holders (usually pharmaceutical companies) must be submitted to the local drug regulator.

Ultimately, pharmacovigilance is the identification of drug-related risks and minimizing the risk of potential harm to the patient. Companies need to conduct comprehensive drug safety and pharmacovigilance audits to assess compliance with global laws, regulations, and policies.

Pharmacovigilance started about 170 years ago, but wasn't labeled that way at the time. They are structured occupational health activities with significant social and commercial impacts aimed at monitoring the balance between drug benefits and risks and improving patient safety and quality of life. In this commentary, we report on the milestones of pharmacovigilance to date in order to understand all the steps that have shaped historic development. From the first reports, which were letters and warnings from clinicians to the editors of important and renowned scientific journals, to today's modern, highly structured electronic records? The historic stage also understands why pharmacovigilance has helped achieve such important results in human health and pharmacology itself, and understands the challenges awaiting pharmacovigilance in the coming years.

Pharmacovigilance is a process which includes:

- Monitor drug use in routine clinical practice to detect previously undetected side effects or changes in the nature of the side effects.
- Risk and benefit assessment of medicines. This will help determine if there are any necessary actions to use the drug more safely.
- Inform healthcare professionals and patients to improve the safe and effective use of medicines.

Why is pharmacovigilance important?

Pharmacovigilance is at the heart of pharmaceutical safety. PV analysis performed in phase I, phase II and phase III clinical trials provides data on the drug safety profile of pharmaceutical companies. This data can be used for further research and development as needed, or submitted to regulatory agencies to enable access to new markets. Both PV practices in clinical research and practices performed by healthcare professionals and consumers provide valuable insights into the safety profile of medicines. If new side effects are identified, the list of side effects on the label should be updated. PV data can lead to drug withdrawal from the market due to dangerous side effects (drug recall).

Key facts of pharmacovigilance

- Pharmacovigilance metrics are specific objective metrics that allow you to assess system, performance, intervention baselines and progress.
- Indicators can measure the presence and performance of pharmacovigilance structures and processes, identify the strengths and weaknesses of pharmacovigilance systems, and indicate their outcomes, growth, or lack of growth.
- Indicators are simple, reproducible, concrete and high so that they can detect pharmacovigilance problems that require attention and changes to the pharmacovigilance system without the need for significant measurement expertise.

What will be the role of pharmacovigilance in the future?

Pharmacovigilance has already changed significantly with the change in law from volume 9A to GMP Guidelines. Patient safety is much more important in the new law. In short, pharmacovigilance plays a much more central role. An example of this is the new

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legislation on sharing safety information between pharmaceutical companies and third parties (such as CROs). The level of detail in this communication needs to be raised, which will undoubtedly have a significant impact not only on the pharmacovigilance team/department, but on the entire life sciences industry. It is clear that pharmacovigilance will continue to play an important and influential role in the development of new drugs and therapies, as the core of life sciences mission is to constantly improve and save the lives of patients around the world.

CONCLUSION

Pharmacovigilance is part of the healthcare system around the world. WHO directs pharmacovigilance operations and provides technical assistance with ADR reporting. Although pharmacovigilance systems are well developed in many countries, the actual incidence of ADR is much higher than reported.

The basic goals of pharmacovigilance are the safe use of medicine, the safety of patients, and ultimately the protection of public health. To achieve this goal, national regulators need to enable healthcare professionals and the general public to report more side effects.