JSTMU Journal of Shifa Tameer-e-Millat University

https://j.stmu.edu.pk

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EDITORIAL

# Current landscape of pharmacovigilance in Pakistan

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***Cite this article as:*** *Zulfiqar Z. Current landscape of pharmacovigilance in Pakistan. JSTMU. 2021; 4(2):75-76.*

**Keywords:** *ADR Reporting, DRAP, medication safety, patient safety, pharmacovigilance*

Pharmacovigilance is the process of evaluation of a new drug molecule for any adverse drug reaction before it is marketed. The history of pharmacovigilance is an old one and dates back to half a century ago. The concept gained momentum after the thalidomide tragedy.[1] it undergoes a lot of studies to make sure that it is safe for human use. During clinical trials, the potential benefits as well as risks of a certain drug molecule are evaluated. This is done in order to introduce a safe and effective drug to the patients. It is important to mention here that the process of pharmacovigilance spans the pre-marketing as well as the post-marketing surveillance. During clinical trials, it is necessary to remain vigilant and document any adverse effects experienced by the subjects enrolled in the trial. After a therapeutic good has been introduced in the market, spontaneous reporting is practiced to scrutinize any life threatening effects. These side effects may be dose dependent or dose-independent and this is the point where consumer reports play an important role.[2] Eradicating any such effects would guarantee patient compliance to the therapy and desired therapeutic outcomes.

In Pakistan, the concept of pharmacovigilance arose after numerous deaths were reported due to administration of counterfeit Tyno cough syrup and adulterated Isotab tablets.[3] These two incidents prove to be monumental and paved way for establishment of Drug Regulatory Authority of Pakistan in 2012 followed by establishment of multiple Drugs Testing Laboratories (DTLs) all over Pakistan. The main objective of these institutions was to standardize the quality of medicines produced within the country and to ensure safe medication therapy for the citizens. In order to play its role in international healthcare community, Pakistan became 134th full member of the WHO Programme for International Drug Monitoring (PIDM) in 2018.[4] Currently, Pakistan National Pharmacovigilance Centre (PNPC) has been designated by DRAP as the national center for reporting Adverse Drug Reactions (ADRs) that collaborates with Uppsala Monitoring Centre (UMC) and analyses ADR reports received from. Provincial Pharmacovigilance Centers (PPC). Special instructions have been issued to regulate the usage of High Alert Medications and Look-Alike & Sound Alike drugs (LASA) medicines.

The role of Primary and Secondary Healthcare Department, Government of Punjab with regard to enabling pharmacovigilance activity in the province is applaud able. The department has designated Pharmacovigilance Officers in all health facilities under its administrative control who are responsible for on-spot detection and reporting of any ADR that may occur. A dedicated portal, Medicine Surveillance System (MSS), has been designed for reporting purpose.[5] It allows the pharmacovigilance officers to report any Therapeutic Goods Related Problem (TGRP).

The scope of pharmacovigilance is vast and it encompasses any adverse drug reactions, adverse drug events, adverse effects following immunization (AEFIs), quality and efficacy issues associated with therapeutic goods and any side effects resulting from misuse, abuse or off-label use of therapeutic goods. As the DRAP Act 2012 regulates the production and use of biologicals, alternative medicine, nutraceuticals, cosmeceuticals along with allopathic medicine, any problems associated with any of these products is reported to pharmacovigilance centers. Here it would be crucial to mention that both PNPC and PPC have designated ADR reporting forms or drug & device complaint (DDC) forms available at respective official websites which can be filled in by the healthcare

professionals or the patients who encountered any ADR and sent to regional pharmacovigilance center. Recently, DRAP also launched a MedSafety mobile app that can be downloaded from App Store and Google Play and allows the user to report any ADRs from their cell phones.

In order to establish a stronger ADR reporting environment, following measures need to be taken.

1. Structured training sessions complying with international standards for focal persons.
2. Establishment of Drug Information Centres (DICs) and Poison Control Centres (PCCs) in all hospitals.
3. Encouraging the physicians, pharmacists, nursing staff & allied healthcare workers to report ADRs.
4. Awareness sessions for public regarding ADR reporting and its benefits.
5. Public awareness campaigns for using ADR reporting forms and MedSafety app.
6. Easily accessible ADR reporting means for the public like the Yellow Card Scheme in UK.
7. Teaching pharmacovigilance to doctors, pharmacists, nurses and allied healthcare providers as part of curriculum.
8. Formulation of National Pharmacovigilance Policy.
9. Allocation of funds for pharmacovigilance activities in Research & Development sector in research institutes and industry.
10. Development of informatics tools including trigger tools with user friendly interface to detect and report ADRs.

The future of pharmacovigilance in Pakistan is seemingly bright as efforts are being made on governmental level to establish an environment that encourages the healthcare professionals to report any unwanted effects experienced by end users of therapeutic goods. It is hoped that soon a successful pharmacovigilance system would be set up all across the country to ensure medication and patient safety.

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