

**Commentary****Pharmacovigilance in Pakistan: A Peek into the Future Prospects**Sarwat Jahan<sup>1</sup>, Shumaila Zahid<sup>2</sup> and Naseer Ahmed<sup>2, 3\*</sup><sup>1</sup>Northwest School of Medicine, Peshawar, Pakistan<sup>2</sup>Department of Basic Medical Sciences, Khyber Medical University, Peshawar, Pakistan<sup>3</sup>Rehman Medical Institute, Peshawar, Pakistan\* [dr.naseer99@gmail.com](mailto:dr.naseer99@gmail.com)**ARTICLE INFO****How to Cite:**Jahan, S. ., Zahid, S. ., & Ahmed, N. . (2021). Pharmacovigilance in Pakistan: A Peek into the Future Prospects: Pharmacovigilance in Pakistan. *Pakistan BioMedical Journal*, 4(2).<https://doi.org/10.54393/pbmj.v4i2.86>

The dire need for drug monitoring and surveillance principles are practices governing the safety profiles of the medicines arose following the 1960's Thalidomide disaster that resulted in phocomelia in thousands of new born babies [1]. Since then Pharmacovigilance centers have been established in the member countries, which report all the untoward drug reactions to Uppsala Monitoring Centre (UMC) that is designated to perform further investigations and global dissemination of the necessary information [2]. Currently 134 countries that are collaborating with UMC of which 96% are developed while 27% are developing countries which are lagging behind as per the unavailability of infrastructure and resources [3].

**Pakistan National Pharmacovigilance Centre (PNPC):**

Ministry of health initiated pharmacovigilance activities in Pakistan in 1994; however a stable system could not be established owing to the unavailability of human resources as well as the infrastructure [4]. Later the suggestion for the establishment of Pakistan National Pharmacovigilance center (PNPC) was mentioned by the national drug policy in 2003 [5], however, the launch of the centre took place in 2012 following the tragic death of around 200 cardiac patients in Lahore as a result of an accidental mixing of Isosorbide mononitrate with Pyrimethamine that resulted in severe deficiency of folic acid, destroying the platelets and causing profuse internal bleeding [6,7]. In the view of the gravity of the situation, an independent authority for drug regulation (Drug regulatory authority of Pakistan - DRAP) was founded under the orders of the Pakistan Supreme Court in 2018. This authority was established for ensuring availability and safety of the medications. In order to devise an infrastructure for the post-marketing drug surveillance, DRAP in collaboration with the Pharmacopoeia of US established PNPC in the year 2017 and by 2018 Pakistan was included as a member in the UMC [8]. The centre has laid down protocols and practices for the international and national coordination and has added Pakistan 134th on the drug monitoring WHO program. Currently the PNPC is being governed by the 2012 Act of DRAP for developing, promoting and regulating the pharmacovigilance system in the country and coordination with provincial sectors to empower the hospitals to establish their own pharmacovigilance centers [9].

**Future Perspectives of PNPC**

PNPC has come a long way still being in infancy and is setting up future goals towards development. Proper guidelines have been formed and an organized system was established by PNPC till 2018 for reporting Adverse Drug Reactions (ADRs) online. Training workshops for the members are regularly carried out to keep the work force ready and updated about the regulatory and management aspects. A regional centre of PNPC was announced to be established in Islamabad in November, 2019 [10].

PNPC has also upgraded its recording, monitoring and reporting system for ADRs via affiliation with the VigiFlow database of the country permitting maximum control locally effectively managing and analyzing the country-wide data [11]. The provincial, market authority and public health stakeholders are called for regular meetings. PNPC has composed comprehensive guidelines and legislation regarding pharmacovigilance protocols that are meant to provide legal surveillance of the activities. In the long run, the PNPC is planning for the establishment of provincial pharmacovigilance centers in each province, and the sub-regional centers and integrating them into the national database. Good practices of pharmacovigilance will utilize the obtained data to bring about safety protocols. However, a number of hurdles are still in the way. There are constraints related to logistics and legal matters as well as finances. There is a requirement of a collaborated effort by all the stake holders in the country. Healthcare professionals have a limited awareness about PNPC protocols and a reluctance to report the adverse events. The main issue is getting the healthcare workers and public normalized and used to with the reporting and surveillance system in order to cope up with the reluctance to report and awareness about the protocols. The success of this system is actually two way and it depends on the response from the reporting stake holders as much as it does on the system of the organization itself. The public health programs, hospitals and healthcare units need to be encouraged to participate in the PNPC system for proper reporting and detection of serious ADRs. Training and awareness sessions need to be conducted to form and normalize a reporting culture among health care workers in Pakistan. Methods for assessment of severity, detection of cause and preventability of the reported ADRs, need further standardization. Furthermore, the international collaboration is still deficient as the WHO data bank does not have any adverse effect reported data from Pakistan; therefore, the gap needs to be filled as a priority. Although a lot still needs to be done, a clear progress has been noted in the past couple of years. With the introduction of new guidelines and strategies; route to further progress is clearly marked but the effort has to involve all the stake holders which will start by the realization and understanding of the significance and need for a properly functional pharmacovigilance system in the country.

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