

## Hardships of drugs monitoring – Ambiguities in pharmacovigilance rules 2018 and guidelines 2019 in the Pakistan

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*Dear Editor,* Medicines are the most significant element of combating ailments and secure a fundamental role in transforming the health status of the population in all healthcare setups in the world. Even though Pakistan is placed amongst the developing countries, it is disappointing that it has been rendered as one of the lower middle-income countries due to many reasons including its malfunctioned healthcare system. Pharmacovigilance (PV) is the monitoring of drugs during the drug development and clinical trials phases; it also covers the entire cycle after the post marketing surveillance phase of the drug i.e. detection, assessment, understanding and reporting of Adverse drug reactions (ADRs) as well.<sup>1</sup> The phases in clinical trials are restricted to a certain population size under special conditions therefore all effects of medicines which are under trials are limited to the involved participants; therefore, it needs to be monitored through a constant channel for eliminating the adverse events of drugs, principally after post marketing surveillance when it is ready to be used by general consumers. In a country like Pakistan, where the self-medication and over the counter (OTC) medicine rate is already very high around 25-75%, the regulations to control this health threat is weak due to the weak regulations.<sup>2</sup>

The Pharmaceutical industry is the living reality since the independence of Pakistan and has potentially evolved with time. As the data presented by Drug Regulatory Authority of Pakistan (DRAP), there are nearly 750 active Pharmaceutical companies out of which 650 are licensed which plays a role in meeting almost 35 percent of domestic demand.<sup>2</sup> The GDP expenditure on health in Pakistan is already very low roughly 0.76 percent, whereas WHO recommends it should be at least six percent.<sup>1</sup>

The culture of reporting adverse events of medicines in Pakistan is not followed because lack of awareness and no PV training of Pharmacists and Physicians in healthcare settings who are the representatives of disseminating PV. Understanding the need for this is also absent which conveniently allows Pharmaceutical industries not to adopt and acknowledge this subject properly mainly due to

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ineffective government regulations. Authorities responsible for implementing these regulations do not have proper workforce and departments for PV. In a country like Pakistan where out of pocket expenditure on medicines is more than 80 percent, the practice of reaching out to clinics for illnesses is not followed instead it is followed by self-medication. This agitation is aggravated due to lack of pertinent professionals in Pharmacies at the hospital and retail pharmacies. WHO also established its Program for International Drug Monitoring in 1968, which covered different member states together with WHO collaborating centre "Uppsala".<sup>3</sup> Recently in 2018, Pakistan has become a full member country of the Uppsala Monitoring Center (UMC). It is then the focus on manufacturing a proper department of PV under DRAP has been generated. The current PV rules 2018 and guidelines draft of Pharmacovigilance in Pakistan<sup>4</sup> is the first step for raising the understanding and need of PV if it is adopted and implemented properly. Formulation of PV policy requires proper dissemination and understanding of this subject. First, it should be taken into consideration of sectors; usually demand is based and depends upon how strict the regulations are imposed on all sectors that govern the responsibility of Pharmacovigilance as part of their functions. Pakistan has not played its role in promoting and ensuring the safe use of drugs because of weak PV channels. Patients, caretakers and consumers cannot report medicine related adverse events due to multiple factors including lack of awareness, no counseling, incapability of Pharmacies, no role of PV in hospital settings etc. Government has not taken control and charge of providing PV setups in hospitals. There is no policy of PV which would help in scaling up the regulations and dissemination of PV in all sectors of health (industry, hospital, pharmacy etc.), PV rules and guidelines of Pakistan are proposed but not effective and implemented until now September 2019.

The current draft of PV Rules and guidelines show the following gaps:

- \* As per WHO's standard for tool kit of Patient safety guidelines and National patient safety policy model, the modes or medium of finance for developing the PV system in hospitals and public settings is missing.
- \* The guidelines/rules draft does not ensure what steps

would be taken if rules are not followed in the public private sector.

- \* Draft of PV guidelines and PV Rules are advanced for the understanding and adoption of national industries and hospital settings as currently, they do not have any Pharmacovigilance trained staff in these settings.

Pakistan's pharmacovigilance rules and guidelines point to a few shortcomings; it appears to be a very ambitious document and looks very promising without any implementation plan, because the ministry and policy board have reservations about a variety of issues such as agenda prioritization, budgets, and workforce other. Strong stakeholders like Pharmaceutical industries are more likely to strengthen by capacity building and national and international coalition. Through their organizational platform, Pharamaceuticals are putting efforts to make a consolidated group of Pharmacovigilance professionals but it needs to be supported by the leadership team of such organizations. As this subject does not fall under the ambit of business principally and is taken as a supporting function, it is therefore not encouraged properly as well. Positions should be created in hospitals for PV officers so it also allows highlighting the role of community Pharmacy and opens window for Pharmacists to practice their clinical Pharmacy, this may also help to reduce the underutilization of qualified Pharmacists in hospital settings.

All stakeholders can devise a solution in form of a standard policy document entailing all possible measures to address the demands of successful implementation and practice to reduce the future mortalities and morbidities due to malpractice of medicine, hospitals, industries, ministries and academia.

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