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Assessing knowledge of the pharmacovigilance system and the contribution of continuing medical education among medical students and active stakeholders

Abstract

Post-marketing surveillance requires the establishment of a system to monitor drug effects in real-world practice, including the collection and analysis of safety data after marketing authorization, known as pharmacovigilance (PV). Healthcare professionals are key elements in PV, as they are directly involved in prescribing, dispensing, and monitoring drug therapy. Their knowledge, clinical experience, and direct access to patients are crucial for the timely detection, assessment, and minimization of risks related to drug use.

Objectives: The main objective of our study is to assess the knowledge and attitudes regarding the PV system among active stakeholders - healthcare professionals (medical doctors, pharmacists, and nurses/medical technicians employed in various positions) and medical students.

Materials and methods: The research was designed as a descriptive-analytical cross-sectional study with MCQ test prepared for assessing the knowledge and attitudes of healthcare professionals and third-year medical students regarding the PV system.

Results: According to this study, employed participants were better informed about the PV system and highly noligable on reporting of adverse reactions, mandatory data in the report as well possible changes in the SmPC and PIL based on reported adverse reactions, and the duties and responsibilities of the QPPV Students demonstrated statistically significantly lower knowledge compared to employed participants, particularly regarding where adverse reactions are reported (75% vs. 100%, p=0.000072), mandatory data in the report (87.76% vs. 100%, p=0.002661), possible changes in SmPC and PIL (73.47% vs. 92.86%, p=0.000381), conditions to report (69.39% vs. 82.86%, p=0.017804), responsibilities of the QPPV (77.55% vs. 95.71%, p=0.016367), and where risk minimization measures are described (65.31% vs. 82.86%, p=0.000271).

Conclusion: These findings highlight the need for systematic strengthening of educational content and continuous medical education in PV, with an emphasis on practical examples, simulations, and direct exposure to adverse reaction reporting procedures.

Keywords: healthcare professionals, students, pharmacovigilance system, knowledge and attitudes

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Iskra Pechijareva Sadikarijo,[1,5] Ognen Petrovski,[2] Ljubuca Lazarevska,[3] Oliver Bushletikj,[4,5] Marija Trajchuleski,[1,5] Marjan Dzeparovski[5,6]

[1]Macedonian Agency for Medicines and Medical devices, Skopje, Republic of North Macedonia
[2]Institute of preclinical and clinical pharmacology with toxicology, Faculty of Medicine, University St. Cyril and Methodius, Skopje, Republic of North Macedonia
[3]Institute of epidemiology and biostatistics with medical informatics, Faculty of Medicine, University St. Cyril and Methodius, Skopje, Republic of North Macedonia
[4]Zan Mitrev Clinic, Clinical Hospital, Skopje, Republic of North Macedonia
[5]Faculty of Medical Sciences, Goce Delcev University, Shtip, Republic of North Macedonia
[6]Bionika Pharmaceuticals, Republic of North Macedonia

Correspondence: Iskra Pechijareva Sadikarijo, Macedonian Agency for Medicines and Medical devices, St. Cyril and Methodius 54, 1000 Skopje, Republic of North Macedonia, Tel 0038975430177

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Abbreviations: MCQ, multiple chose questionnaire; QPPV, qualified person for pharmacovigilance; SmPC, summary of product characteristics; PIL, patient information leaflet; MALMED, Macedonian agency for medicines and medical devices; PV, pharmacovigilance; ADR, adverse drug reaction; CNS, central nervous system; PSUR, in periodic safety update reports; RMP, risk management plan; EMA, european medicine agency

Introduction

Drug safety represents one of the key aspects in the process of drug development and use. A drug is considered safe if its expected benefits significantly outweigh the potential risks of adverse reactions when used appropriately.[1,2] Nevertheless, every drug can cause adverse effects — varying in frequency, form, and severity.

Each new drug undergoes a pre-marketing phase, which is a complex and extensive process consisting of preclinical studies on experimental animals (to assess toxicological properties, pharmacokinetics, and potential efficacy) and clinical trials in humans (divided into three phases, designed for the systematic evaluation of safety, efficacy, and the benefit–risk ratio, based on a pre-approved protocol, in strictly selected participants from a defined patient population, for a specific indication).[3] However, these studies are performed on a limited number of subjects and within a restricted timeframe, providing data on the most common adverse reactions, but not on rare or delayed effects.[2]

Following drug registration, i.e., approval by a regulatory authority, the drug is placed on the market and used in everyday clinical practice in a broader, uncontrolled, and more diverse population. This increases the likelihood of new, rare, or unexpected serious reactions, unknown effects of long-term use, drug–drug interactions in patients receiving multiple therapies, medical errors (arising from complex regimens or look-alike/sound-alike drug names), off-label use (beyond the approved indication), misuse or abuse (particularly in psychoactive drugs), and administration in vulnerable groups such as children, the elderly, pregnant or breastfeeding women, and patients with chronic conditions (e.g., hepatic or renal insufficiency).[1,4,5]