THE IMPORTANCE OF MEDICAL LITERATURE MONITORING IN PHARMACOVIGILANCE - ACHIEVEMENTS AND CHALLENGES

Miloš Stoiljković[1*], Gordana Pejović[1,2]

[1]SGS Belgrade Ltd., Belgrade, Serbia
[2]University of Belgrade - Faculty of Organisational Sciences, Department of Quality Management and Standardization, Belgrade, Serbia

*milos.stoiljkovic@sgs.com

According to the U.S. Food and Drug Administration (FDA), scientific and medical literature is among the four largest sources of adverse drug reactions (ADR) reporting. The aim of this work was to highlight the growing potential of medical literature search in conducting pharmacovigilance (PV) activities, summing up the most common challenges facing pharmaceutical industry in this field. A special emphasis was given to examination of Individual Case Safety Reports (ICSRs) publication frequency in medical literature over the past 15 years in the Republic of Serbia. A comprehensive review of published scientific papers, national and international PV guidance's, and screening of websites of the relevant Contract Research Organizations experienced in medical literature monitoring for PV purposes has been carried out. Individual cases of ADRs published by Serbian authors in relevant medical journals have been identified by conducting a global Embase search. A significant overall increase in the number of case reports was identified. This showed a positive correlation with the number of ADR reports. Systematic review of medical literature appears to be an important tool especially for signal detection (1). In Serbia, a significant increase of ICSR literature reports has been recorded since 2010, mostly as the result of improvements in applying a good PV practice and the increasing development and availability of modern communication channels and global database use (2). However, adequate selection of local, non-indexed medical literature still appears to be one of the biggest challenges for pharmaceutical industry given the lack of clear regulatory guidance's.

References

1. Ochyra B, Szewczyk M, Przybylkowski A. Impact of literature reports on drug safety signals. Wien Klin Wochenschr 2021; 133:188–193.
2. ALIMS. Godišnji izveštaji rezultata spontanog prijavljivanja neželjenih reakcija na lekove. Available at: https://www.alims.gov.rs/farmakovigilanca/godisnji-izvestaji/ (Last time accessed on 06-Jun-2022)

ZNAČAJ PRAĆENJA MEDICINSKE LITERATURE U FARMAKOVIGILANCI – DOSTIGNUĆA I IZAZOVI

Miloš Stoiljković[1*], Gordana Pejović[1,2]

[1]SGS Beograd d.o.o, Beograd, Srbija
[2]Univerzitet u Beogradu – Fakultet organizacionih nauka, Katedra za menadžment kvaliteta i standardizaciju, Beograd, Srbija

*milos.stoiljkovic@sgs.com

Prema podacima Američke agencije za hranu i lekove (FDA), naučna i medicinska literatura spada među četiri najveća izvora prijavljivanja neželjenih reakcija na lekove. Cilj ovog rada je da se istakne rastući potencijal pretraživanja medicinske literature u farmakovigilanci, ali i sumiraju najčešci izazovi sa kojima se farmaceutska industrija suočava na ovom polju. Poseban osvrt dat je ispitivanju trenda publikovanja pojedinačnih slučajeva neželjenih reakcija na lekove (*Individual Case Safety, Reports-ICSRs*) u prethodnih 15 godina u Republici Srbiji. Izvršen je sveobuhvatan pregled objavljenih naučnih radova, nacionalnih i međunarodnih smernica iz oblasti farmakovigilance, kao i pregled internet prezentacija relevantnih ugovornih istraživačkih organizacija sa iskustvom u pretraživanju medicinske literature za potrebe farmakovigilance. Pojedinačni slučajevi neželjenih reakcija na lekove objavljeni u relevantnim medicinskim časopisima od strane autora u Republici Srbiji, identifikovani su pretragom globalne baze *Embase.* Primećen je porast broja studija slučajeva objavljenih u medicinskoj literaturi, koji je u pozitivnoj korelaciji sa brojem identifikovanih neželjenih reakcija na lekove. Posebno se ističe značaj sistematskog posmatranja medicinske literature primenom globalnih baza podataka u cilju detekcije signala (1). U Republici Srbiji, značajan porast *ICSR i*zveštaja poreklom iz literature beleži se od 2010. godine kao posledica poboljšanja u primeni dobre prakse u prijavljivanju ali i sve većeg razvoja i dostupnosti savremenih kanala komunikacije i globalnih baza podataka (2). Adekvatna selekcija lokalne, neindeksirane medicinske literature se trenutno čini jednim od većih izazova za farmaceutsku industriju s obzirom na nedostatak dovoljno jasnih preporuka regulatornih tela.

Literatura

1. Ochyra B, Szewczyk M, Przybylkowski A. Impact of literature reports on drug safety signals. Wien Klin Wochenschr 2021; 133:188–193.
2. ALIMS. Godišnji izveštaji rezultata spontanog prijavljivanja neželjenih reakcija na lekove. Dostupno na: https://www.alims.gov.rs/farmakovigilanca/godisnji-izvestaji/ (Poslednji pristup: 06-Jun-2022)