

POSTMARKETING RESEARCH IN PHARMACY

Oliinyk O.E., Evtushenko O.M.

The National University of Pharmacy, Kharkiv, Ukraine

oleinyk_nfau@mail.ru

Postmarketing surveillance (also post market surveillance) is the practice of monitoring the safety of a pharmaceutical drug or medical device after it has been released on the market and is an important part of the science of pharmacovigilance. Since drugs are approved on the basis of clinical trials, which involve relatively small numbers of people who have been selected for this purpose - meaning that they normally do not have other medical conditions which may exist in the general population - postmarketing surveillance can further refine, or confirm or deny, the safety of a drug after it is used in the general population by large numbers of people who have a wide variety of medical conditions.

Postmarketing surveillance uses a number of approaches to monitor the safety of licensed drugs, including spontaneous reporting databases, prescription event monitoring, electronic health records, patient registries and record linkage between health databases.

Postmarketing research conducted to support the use of the medicine and begin by marketing or medical departments of pharmaceutical companies. More often they are following types of studies:

- comparative studies of company product and main medicines competitors;
- comparative analysis of dosage forms and dosage;
- research of effects of the drug on quality of life (QoL);
- analysis of the interaction with concomitant treatments;
- additional pharmacovigilance data on broader populations and longer duration exposure;
- product uptake and public perception “Real-life” practices for treatment of disease;
- health information and education;
- hypothesis generation and publication support.

These studies are not required to obtain the approval by licensing authorities. But doctors, pharmacists and other staff providing health services, pay much attention to the results of postmarketing research during the appointment of the drug to the patient. Postmarketing research can provide unique and valuable data for a wide range of stakeholders, including regulatory agencies, sponsors, and payers, physicians, and their patients.