

**Lachoo Memorial College of Science & Technology (Autonomous), Jodhpur**

**Pharmacy - Wing**

**Project Work**

**Synopsis**

**‘Scope of Pharmacovigilance in India’**

**Supervised by:** **Submitted by:**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_

**Mrs. Ruchi Agarwal** **Bharat Solanki**

Assistant Professor

Department Of Pharmaceutical Chemistry B. Pharm. VIII Sem. (2022-2023)

Approved by: Title verified by:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

### Prof. Dr. G. K. Singh Dr. P. K. Choudhary

### Director

Convener Project Work Committee

Date of submission:

**Abstract:**

Pharmacovigilance (PV) plays a key role in the healthcare system through assessment, monitoring and discovery of interactions amongst drugs and their effects in human. Pharmaceutical and biotechnological medicines are designed to cure, prevent or treat diseases; however, there are also risks particularly adverse drug reactions (ADRs) can cause serious harm to patients. Thus, for safety medication ADRs monitoring required for

each medicine throughout its life cycle, during development of drug such as pre-marketing including early stages of drug design, clinical trials, and post-marketing surveillance. PV is concerns with the detection, assessment, understanding and prevention of ADRs. Pharmacogenetics and pharmacogenomics are an indispensable part of the clinical research. Variation in the human genome is a cause of variable response to drugs and susceptibility to diseases are determined, which is important for early drug discovery to PV. Moreover, PV has traditionally involved in mining spontaneous reports submitted to national surveillance systems. The research focus is shifting toward the use of data generated from platforms outside the conventional framework such as electronic medical records, biomedical literature, and patient-reported data in health forums. The emerging trend in PV is to link premarketing data with human safety information observed in the post-marketing phase. The PV system team obtains valuable additional information, building up the scientific data contained in the original report and making it more informative. This necessitates an utmost requirement for effective regulations of the drug approval process and conscious pre and post approval vigilance of the undesired effects, especially in India. Adverse events reported by PV system potentially benefit to the community due to their proximity to both population and public health practitioners, in terms of language and knowledge, enables easy contact with reporters by electronically. Hence, PV helps to the patients get well and to manage optimally or ideally, avoid illness is a collective responsibility of industry, drug regulators, clinicians and other healthcare professionals to enhance their contribution to public health. This review summarized objectives and methodologies used in PV with critical overview of existing PV in India, challenges to overcome and future prospects with respect to Indian context.

**Keywords:** Pharmacovigilance, Adverse drug reaction, Clinical trials, Pharmacogenomics, Data mining, Indian Pharmacopoeia Commission

**Chapter Plan**

1. Introduction
2. Clinical Trails in India
3. Role of Pharmacogenomics in PV
4. Data Mining For PV
5. PV in India
6. Conclusion
7. References

**References**

**1.** McBride WG. 1961. Thalidomide and congenital abnormalities. Lancet. 278, 1358 10.1016/S0140-6736(61)90927-8

**2.** Bégaud B, Chaslerie A, Haramburu F. 1994. Organization and results of drug vigilance in France. Rev Epidemiol Sante Publique. 42, 416-23.

**3.** WHO. The Importance of Pharmacovigilance, Safety Monitoring of medicinal products. World Health Organization 2002.

**4.** Report E. Effective communications in Pharmacovigilance. International Conference on Developing Effective Communications in Pharmacovigilance, Erice, Sicily 1997; 24-27.

**5.** Shuka SS, Gidwani B, Pandey R, Rao SP, Singh V, et al. 2012. Importance of Pharmacovigilance in Indian Pharmaceutical Industry. Asian J. Res. Pharm. Sci. 2, 4-8.

**6.** Hornbuckle K, Wu H-H, Fung MC. 1999. Evaluation of spontaneous adverse event reports by primary reporter - a 15-year review (1983 to 1997). Drug Inf J. 33, 1117-24.

**7.** WHO 2000. Consumer reporting of ADRs. WHO Drug Information. 14, 211-15.

**8.** Egberts GPG, Smulderes M, De Konig FHP, et al. 1996. Can adverse drug reactions be detected earlier?: a comparison of reports by patients and professionals. BMJ. 313, 530-31.

**9.** Norwood PK, Sampson AR. 1988. A statistical methodology for postmarketing surveillance of adverse drug reaction reports. Stat Med. 7, 1023-30.

**10.** WHO. Immunization safety surveillance: Guidelines for managers of immunization programmes on reporting and investigating adverse events following immunization. Immunization Focus: WHO Regional Office for the Western Pacific. Manila 1999.

**11.** WHO. Global programme for vaccines and immunization: Expanded Programme on Immunization. Surveillance of adverse events following immunization: Field guide formanagers of immunization programmes. Geneva 1997.

**12.** Simonsen L, Kane A, Lloyd J, Zaffran M, Kane M. 1999. Unsafe injections in the developing world and transmission of bloodborne pathogens: a review. *Bull World Health Organ*. 77, 789-800.

**13.** Strom BL. Overview of automated databases in pharmacoepidemiology (ed). Pharmacoepidemiology Chichester. UK, John Wiley & Sons. 2005;p.219–22.

**14.** Butlen S, Ducuing F. 2010. European medicines agency support mechanisms fostering orphan drug development. Drug News Perspect. 23, 71-81. 10.1358/dnp.2010.23.1.1437303

**15.** Giezen TJ. 2009. Evaluation of post-authorization safety studies in the first cohort of EU risk management plans at time of regulatory approval. Drug Saf. 32, 1175-87.

**16.** Herret E. 2010. Validation and validity of diagnoses in the general practice research database. J Clin Pharmacol. 69, 4-14.

**17.** Abenhaim L. 1996. Appetite-suppressant drugs and the risk of primary pulmonary hypertension. N Engl J Med. 335, 609-16.

**18.** Kaufman DW. 2001. Signal generation and clarification: Use of case-control data. Pharmacoepidemiol Drug Saf. 10, 197-203.

**19.** Greene W. The Emergence of India’s Pharmaceutical Industry and Implications for the U.S. Generic Drug Market. U.S. International Trade Commission 2007.

**20.** Iskander J. 2005. Monitoring vaccine safety during an influenza pandemic. Yale J Biol Med. 78, 265-75.

**21.** Stefano F, Tokars J. 2010. H1N1 vaccine safety monitoring: Beyond background rates. Lancet. 375, 1146-47.

**22.** Chen RT. 2000. The vaccine safety datalink: Immunization research in health maintenance organizations in the USA. Bull World Health Organ. 78, 186-94.

**23.** Vander H, Stichele R. 2004. European Surveillance of Antimicrobial Consumption (ESAC): Data collection performance and methodological approach. Br J Clin Pharmacol. 58, 419-28.

**2**4. Martirosyan LA. 2010. Systematic literature review: Prescribing indicators related to type 2 diabetes mellitus and cardiovascular risk management. Pharmacoepidemiol Drug Saf. 19, 319-34.

**25.** Von NC, Schwappach DL, Koeck CM. 2003. The epidemiology of preventable adverse drug events: A review of literature. Wien Klin Wochenschr. 115(12), 407-15.

**26.** Aneesh TP, Sonal Sekhar M, Jose A, Chandran L, Zachariaha SM. 2009. Pharmacogenomics: The Right Drug to the Right Person. J Clin Med Res. 1, 191-94.

|  |
| --- |
| **WORK SCHEDULE TABLE** |

## Criteria for Award of Marks for Timely Submission -

|  |  |
| --- | --- |
| **Time duration of Synopsis/ Project work proofs and final report submission** | **Marks to be Awarded (5)** |
| Timely Submission | 5 |
| One week after the last date of submission | 3 |
| Two weeks after the last date of submission | 1 |
| After two weeks of the last date of submission | 0 |

**Students are required to get this table filled by the respective supervisor at the time of submission of Synopsis/ Project work final report.**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Criteria** | **Due date for submission** | **Due Date** | **Submission Date** | **Marks Awarded** | **Signature of supervisor** |
| Submission of Synopsis  **Max marks: 5** | As per the synopsis submission notice |  |  |  |  |
| Submission of project work final report in the prescribed format  **Max marks: 5** | As per the report submission notice |  |  |  |  |
| Internal assessment by the supervisor  *(Based upon regularity, sincerity and quality of work of the student)*  **Max marks: 10** | | | |  |  |
|  | | | **Total Marks (20)** |  |  |