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Review on Pharmacovigilance

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Abstract: Pharmacovigilance involves the science and practice of identifying, evaluating, understanding, and preventing adverse effects or other issues related to drugs. The legal framework governing pharmacovigilance for medicinal products in the EU/European Economic Area (EEA) is outlined in a series of Directives that detail the responsibilities of marketing authorization holders and regulatory agencies. Experiences from the past two decades with medicines have highlighted the crucial need for a systematic approach to studying drug safety and managing drug risks. Among all the fields discussed in this chapter, pharmacovigilance has particularly advanced within the pharmaceutical industry and its regulatory bodies.

I. INTRODUCTION

The total value of pharmaceutical product exports amounts to Rs. 40,000 crore. India has also become a center for clinical trials as well as drug discovery and development. Furthermore, a growing number of drug entities, which include new chemical entities, are being introduced. This includes pharmaceutical products, vaccines, various dosage forms, new routes of administration, and new therapeutic claims for existing drug substances. Pharmacovigilance holds greater significance for recently developed medications since data acquired from clinical trials are insufficient to address all facets of drug safety. Pharmacovigilance, it is primarily split into pre-marketing (during the clinical phase) and post-marketing phases, starts during the clinical phase and extends to every step of the drug's lifecycle.The procedure for gathering such data regarding a medication commences in phase I of the clinical trial, prior to the drug's approval, and continues even after it receives approval; numerous post-marketing safety studies are carried out, with many being mandated by global drug regulatory authorities.

A. The goal or aim of Pharmacovigilane

1) Improve safety for patients precautions
2) To promote the secure and reasonable use of medicines
3) Enhance public defenses against innovative goods
4) To reduce the risk of medicine
5) Improving benefit of medical care
6) Elimination of adverse effects
7) Stimulate improving and therapeutic instruction

B. The history of Pharmacovigilance

Following serious adverse reactions coming from giving Thalidomide to pregnant women, pharmacovigilance was officially launc hed in Great Britain in 1961.However, the history of pharmacovigilance has been marked by several types of events.
This is the evolution from its beginnings in 1848, first chloroform originated, to its existing status.

1) In 1848, Hannah Greener, afterwards fifteen, falls ill with chloroform harming after getting operation to remove an ingrown toenail.Chloroform was initially employed in medical procedures earlier year, replacing ether, which caused more severe nausea and vomiting;
2) In 1937, over one hundred Americans were infected via a sulfanilamide elixir;
3) The Federal Food, Drug, and Cosmetic Act proceeds by the United States Congress in 1938;
4) In 1955, acetylsalicylic acid is identified as a cause of gastrointestinal disorders;
5) In 1961, a letter from Australian physician William McBride appears in “The Lancet.” He discusses the rise in cases of malformed lower limbs in infants born to mothers who used thalidomide during pregnancy;
6) In 1964, the UK adopted the Yellow Card system for reporting adverse chemical reactions;
7) In 1965, Council Directive 65/65/EEC is introduced on January 26, addressing the alignment of legal provisions regarding proprietary medicinal products;
8) The World Health Organization's Program for International Drug Monitoring is established in 1968;

9) In 1995, the European Medicines Agency is founded;
10) In 2001, the EudraVigilance database is established;
The European Parliament and Council adopted Directive 2010/84/EU in 2012, that modified the pharmacovigilance regulations in Directive 2001/83/EC. The EudraVigilance system was altered and launched in 2017.

C. Pharmacovigilance Methods

1) A process of balanced assessment [15]
This method analyzes a case report through a selection of visual analog scale (VAS) models, ensuring every criterion can be conside red separately.
This approach's primary benefit is that, instead of tackling various causative parameters as distinct issues. it analyzes them as likely results in. Multiple assessors evaluate each case separately.

2) The Australian method [18]
The Australian method took into consideration details that helps draw conclusions, such duration and lab data from case reports which are given, as well as previous knowledge regarding the suspect drug profile.

3) The Ciba-Geigy method [16]
The Ciba-Geigy process involves the outcome of expert consensus conversations. For evaluation of negative drug reactions to determine connection on a VAS, these specialists use their clinical judgment. This approach make use of a checklist containing 23 questions break into smaller three categories: (i) the adverse reaction's history, (ii) the patient's former adverse reaction history, and (iii) monitoring-physiological aspects

D. ICH Guidelines
Objectives of the Regulations As a way to support human clinical trials of a particular nature, duration, and marketing authorization, this document establishes international requirements for and facilitates harmonisation of nonclinical safety research. In standardizing the guidelines for nonclinical safety searches, it will be simple to develop the current recommendations as well as less probable that it will result in substantial regional variations.
Similar to the 3R (reduce/refine/replace) principles, this guidance should make it easier to conduct clinical trials on time, minimize the use of animals, and utilize fewer resources for drug development. This should promote the safe and legal investigation and accessibility of novel medicines.
pharmacokinetic studies, genotoxicity studies, reproductive damage studies, and evaluations of carcinogenic risks associated with drugs that are particularly concerning or intended for prolonged use. Further nonclinical studies, including studies on toxicity, immunotoxicity, toxicity in growing livestock, and abuse potential, need to be conducted when required. This guideline covers such types of examinations as they influence how human clinical trials are carried out. The suggestion should be seen as providing general guidance for drug development as it includes situations that usually arise in the standard pharmaceutical study procedure. The preparation and execution of human clinical trials and animal safety studies ought to utilize an approach that is both ethical and scientifically appropriate for the drug being studied under

E. Drugs Controller General of India (DCGI)
The Central Drugs Standard Control Organization of the Government of India is controlled from DCGI, which is in responsible for granting licences for particular drug categories in India, includes blood and blood products, IV fluids, vaccines, and sera. The Ministry of Health & Family Welfare is in control of the Drugs Controller General of India.[1] In addition, DCGI sets regulations for drugs manufacturing, distribution, imports, and sales in India.
The responsibilities of the DCGI encompass the following:
1) Licensing: Issuing approvals for licenses related to various categories of medications, including blood and blood products, intravenous fluids, vaccines, and sera.
2) Regulatory Oversight: keep watch on the production, sale, importation, and distribution of medical equipment, cosmetics, and pharmaceuticals.
3) Standard Setting: Setting regulations for the producer, distribution, shipment, and sale of pharmaceuticals in India.
4) Appellate Authority: Acting as a governing authority for matters regarding conflicts over the quality of medicines.

5) Clinical Trial Oversight: Managing and granting permissions for clinical trials to ensure the safety and effectiveness of novel drugs and medical devices.
6) Pharmacovigilance: Tracking the performance of drugs post-marketing through the Pharmacovigilance Program of India (PvPI).
7) New Drug Approval: Authorizing new medications and biosimilars.
8) Enforcement: Ensuring adherence to the Drugs and Cosmetics Act and associated regulations
9) Instruction and Assistance: Educating Drug Analysts and collaborating with state licensing agencies.
10) Medical Equipment Regulation: controlling medical devices, including those regulated by the 2017 Medical Device Rules.

The Central Drugs Standard Control Organisation (CDSCO), operating under the Directorate General of Health Services within the Ministry of Health and Family Welfare of the Government of India, serves as the National Regulatory Authority (NRA) for the country. Its headquarters is situated at FDA Bhawan, Kotla Road, New Delhi 110002, and it includes seven laboratories, thirteen port offices, four sub-zonal offices, and six zonal offices. distributed throughout India.

The Drugs and Cosmetics Act of 1940, along with the associated rules established in 1945, assigns various responsibilities to both central and state regulators for the oversight of drugs and cosmetics. This framework aims to ensure the consistent application of the Act and its rules, thereby safeguarding the safety, rights, and well-being of patients through the regulation of these products. In order to guarantee the safety, effectiveness, and quality of the medical products produced, imported, and disseminated inside the nation, CDSCO is continuously striving to promote transparency, accountability, and standardization in its services.

F. Responsibilities of CDSCO:

1) Drug Approval: CDSCO evaluates and approves new drugs and clinical trials, ensuring that drugs are safe, effective, and of high quality before they are available in India.
2) Setting Standards: CDSCO defines the standards for pharmaceuticals, cosmetics, diagnostics, and medical devices.
3) Import Regulation: CDSCO oversees the importation of drugs to ensure compliance with Indian standards and regulations.
4) Clinical Trial Oversight: CDSCO governs clinical trials in India to ensure they are carried out ethically and safely.
5) Licensing: CDSCO grants licenses for the manufacturing, transportation, and exporting of medical devices and pharmaceuticals.
6) Quality Control: CDSCO supervises the quality of drugs and cosmetics produced in India and those brought in from abroad.
7) Adverse Drug Reaction Monitoring: CDSCO tracks adverse drug reactions and implements pharmacovigilance programs.
8) Coordination with State Agencies: CDSCO collaborates with State Drug Control Organizations to promote consistent enforcement of the Drugs and Cosmetics Act.
9) Policy Guidance: CDSCO offers policy advice and expert recommendations to state drug control organizations.
10) Enforcement: CDSCO implements the Drugs and Cosmetics Act's regulations, which prohibit the retailing of substandard medicines and cosmetics.

G. Career prospects

1) Individuals with training in pharmacology and clinical trials research will discover a variety of promising job opportunities, including
2) Entry-level clinical research associate
3) Data management specialist
4) Auditors for clinical trials
5) Medical writer
6) Clinical data specialist
7) Drug safety officer
8) Project manager for clinical trials
9) Clinical research supervisor
10) Manager of regulatory affairs

II. CONCLUSION

Pharmacovigilance fundamentally relies on both the qualitative and quantitative analysis of spontaneous reports of adverse drug reactions, followed by a clinical evaluation regarding its influence on the drug's overall safety profile. The Indian pharmaceutical sector ranks as the third largest by volume and the thirteenth largest by value.

The market is primarily led by branded generic medications, which account for approximately 70-80% of total market share. Thus, establishing a standardized pharmacovigilance framework for monitoring drug ADRs and ensuring patient safety is essential. The reporting of ADRs post-marketing should be proactively promoted and should involve all stakeholders, including healthcare professionals such as doctors, pharmacists, nurses, and pharmaceutical companies.

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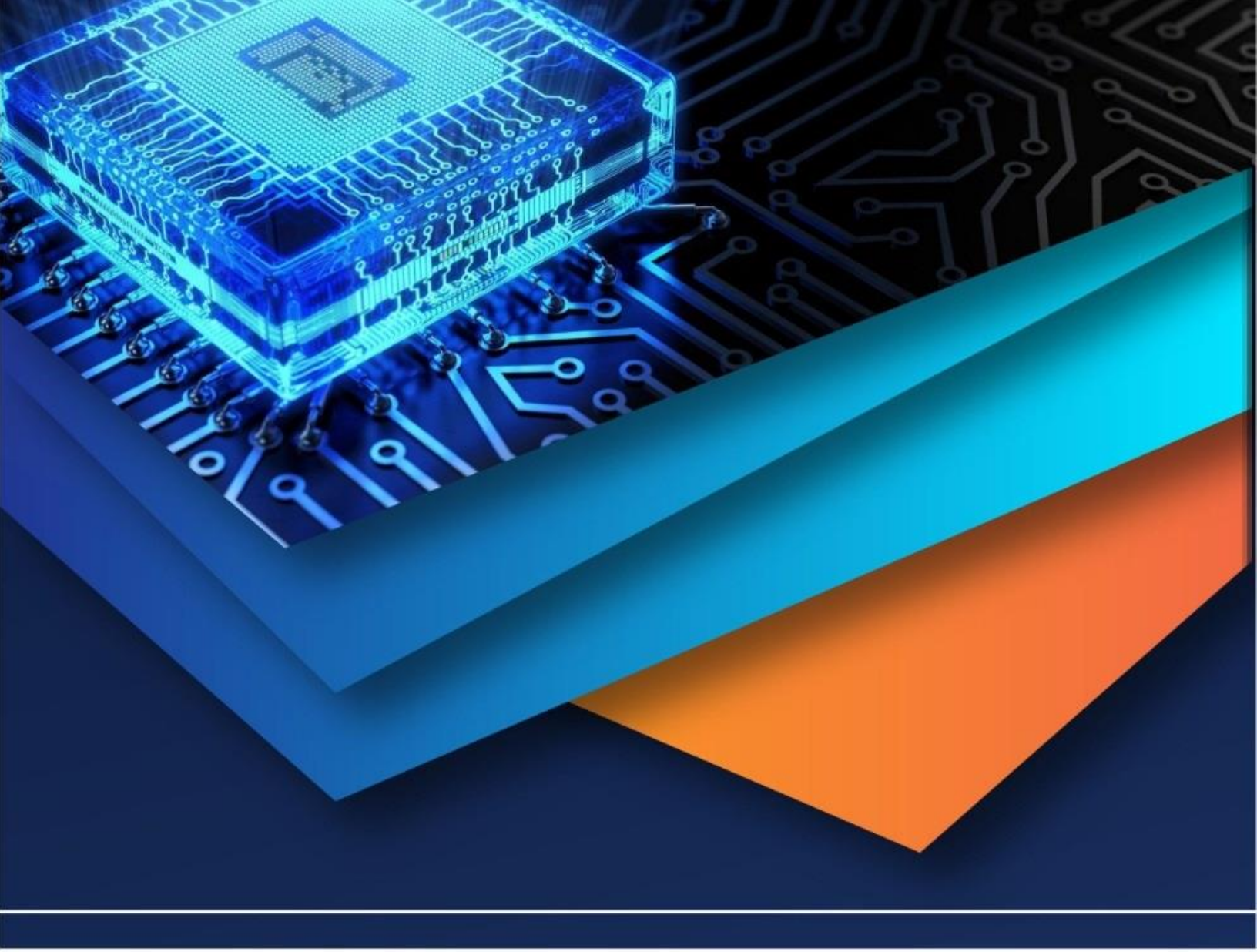

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