e-ISSN: 2582-5208
International Research Journal of Modernization in Engineering Technology and Science
(Peer-Reviewed, Open Access, Fully Refereed International Journal)
Volume:06/Issue:12/December-2024 Impact Factor- 8.187 www.irjmets.com

PHARMACOVIGILANCE AND IT'S SIGNIFICANCE

Trupti P Shinde*1, Aditya D Dhiwar*2, Gaurav P Dhanwde*3, Harshal B Funde*4, Naman K Gandhi*5

*1Professor, Department Of Pharmacy Practice Arihant College Of Pharmacy, Kedgaon, Ahmednagar, Maharashtra, India.

*2,3,4,5Student, Department Of Pharmacy Practice Arihant College Of Pharmacy, Kedgaon, Ahmednagar, Maharashtra, India.

ABSTRACT

Pharmacovigilance defined by the world health organization as "the science and activities relating to the detection, assessment, understanding, assessment and prevention of adverse effects or any other drug related problems". It plays a key role in ensuring that patients receive safe drugs. Our knowledge of a drug's adverse reactions can be increased by various means, including spontaneous reporting, intensive monitoring and database studies. New processes both at a regulatory and scientific level are being developed with the aim of strengthening pharmacovigilance.

Keywords: Drug Regulation, Drug Safety, Intensive Monitoring, Pharmacovigilance, Spontaneous Reporting, Transparency.

I. INTRODUCTION

Pharmacovigilance is the science and activities relating to detection, assessment, understanding and prevention of adverse effects or any other drug related problems. These adverse drugs reactions (ADRs) not only add to suffering of patients but also increase morbidity and mortality along with a financial burden on society. The overall incidence of ADRs in hospitalized patients is estimated to be 6.7% (range 1.2-24.1%) and that of fatal ADRs 0.32% (0.1-0.85%[2])]. Data indicates that in patients who experience ADRs, death rates are 19.18% higher and the length of hospital stay is 8.25% higher. Total medical cost for patients with ADRs are increased by an average of 196. However the lack of ability of clinicians to suspect or detect such adverse events related to drugs might lead to inappropriate management of adverse events, thus exposing the patients to additional drug hazards. To minimize the suffering of the patients from ADRs, though difficult, it is essential to establish casual relationship between the drug and the event which is the causality assessment. By definition, Causality assessment is the evaluation of the likelihood that a particular treatment is the cause of an observed Adverse E[4v]eInt ta.ssesses the relationship between a drug treatment and the occurrence of an adverse even. It is an important component of pharmacovigilance, contributing to better evaluation of the risk-benefit profiles of medicine[s5] and is an essential part of evaluating ADR reports in early warning systems and for regulatory purpose[6s] .

II. ADVERSE DRUG REACTION

At a normal dose sometimes the given medications may harm the patients which are called Adverse Drug Reactions (ADR)[7.] Adverse drug reaction is different from side effect. The evaluation of ADRs is most critical in the field of pharmacovigilance.

Concerning marketed remedies, a suitable definition of an adverse drug reaction is as follows:

1. Unlisted/Unexpected Adverse Drug Reaction

An adverse reaction is the nature or harshness of drug which is not reliable with the proper product data available at the time of clinical tr[i7a]ls.

Company is needed help during investigators brochure for an unapproved drug. Brief summary of drug data sheet for an official product.

2. Listed / Expected Adverse Drug Reaction

The information about ADR like nature or severity and specificity of the drug is already recorded[8.]

ADVERSE DRUG REACTIONS REPORTING

When the adverse reaction to drugs is potentially serious or clinically important, all health care workers

e-ISSN: 2582-5208
International Research Journal of Modernization in Engineering Technology and Science
(Peer-Reviewed, Open Access, Fully Refereed International Journal)
Volume:06/Issue:12/December-2024 Impact Factor- 8.187 www.irjmets.com

including doctors, pharmacists, nurses and other health experts are requested to clarify it. It is necessary to report an adverse drug reaction to pharmacovigilance.

SPONTANEOUS REPORTING SYSTEM

1. Regionalization
2. Repossession of further data
3. Access to all important pre and post marketing information
4. Detailed drug utilization data.
5. Standardized Evaluation of causality and significance

6. Encouragement

Documentation of ADRs

The pharmacovigilance curriculum conveyed worldwide motivate that all suspected drug- related adverse events should be outlined. It takes interests on reports of the following:

1. Every adverse effect suspected or occurred by new drugs and drugs of current issue
2. Documentation of various drugs that cause ADRs, which include death, life-threatening conditions, disability, hospitalization and congenital abnormalities.

The significant adverse reaction of any drug should be notified within seven days. The other facts related to adverse events should be informed within eight days. (Bates et al. 1995: Classen et al 1997). The ADR form can be collected through any pharmacovigilance centre. After reviewing the form, the centre forwards it to the regional centre and after that, it is propelled to the zonal centre (Goldman 1998: Palaian et al. 2006: Ravi Shankar et al. 2010). The details are then statistically inspected and forwarded to WHO-Uppsala Monitoring committee (UMC)[.9]

PROCEDURE FOR REPORTING ADRs

It is the first duty of any pharmacovigilance centre to report all suspected adverse events of the drug if found. Information regarding ADRs that should be reported and tabulated.

Elements in ADR reporting

What should be reported?

Necessary information others

Adverse reaction of drugs Medication over dose, ph.defect

Who can report staff

When it can be reported How to report

Doctors, Pharmacists, Nurses All government and private hospital

Any adverse reaction if noticed

Through completely filled yellow for

Where it can be reported

Complete filled ADR form should be submitted to PVpI. --

Monitoring of ADRs

ADR monitoring is the practice of continuously monitoring the undesirable effects caused using any drug. Pharmacovigilance plays an imperative impersonation in monitoring ADRs.[10]

It is inherent for pharmaceutical regulators to screen their pharmaceutical products in the market and record if any suspected adverse reactions are identified. ADRs can occur by use of various pharmaceutical products, herbal drugs, cosmetics, medical devices, biological etc. Introducing this monitoring procedure intends at warranting that patients to receive safe and beneficial medicinal products.{Karch and Lasanga 1997}.

If any of the adverse events are not stated, it may result in noxious and serious effects of remedial products. Thus properly conducting ADR monitoring programs will help to reduce the harmful effects of therapeutic products.

e-ISSN: 2582-5208
International Research Journal of Modernization in Engineering Technology and Science
(Peer-Reviewed, Open Access, Fully Refereed International Journal)
Volume:06/Issue:12/December-2024 Impact Factor- 8.187 www.irjmets.com

Benefits of ADR monitoring

An ADR monitoring and reporting program can furnish following benefits:

1. It caters information about quality and safety of pharmaceutical products.
2. It initiates risk-management plans.
3. It prevents the predictable adverse effects and helps in measuring ADR adherence.
4. It instructs health care team i.e., patients, pharmacists and nurses about adverse drug effects and creates awareness regarding ADRs.

The main objective of ADR monitoring is to disclose the quality and frequency of ADRs and to identify the risk factors that can cause the adverse reac[1t0io] ns.

Serious Adverse Event

A serious adverse event (SAE) in human drug trials are defined as any untoward medical occurrence that is caused at any dose

(a) Results in death

(b) Is life threatening

(c) Require in-patient hospitalization

(d) Prolongation of existing hospitalization

(e) Causes congenital anomaly/birth def[e11c]t.

Investigators in human clinical trial are obligated to report these events in clinical study reports. Research suggests that these events are often inadequately reported in publicly available report[s1.2]

Pharmacovigilance in India India has more than half a million qualified doctors and 15,000 hospitals having a bed strength of 6,24,000. It is the fourth largest producer of pharmaceuticals in the world. It is emerging as an important trial hub in the world. Many new drugs are introduced in our country. Therefore, there is a need for a vibrant pharmacovigilance system in the country to protect the population from the potential harm that may be caused by some of these new drugs. Clearly aware of the enormity of task the Central Drugs Standard Control Organization (CDSCO) has initiated a well structured and highly participative National pharmacovigilance program. It is largely based on the recommendations the WHO document titled "safety monitoring of medicinal products- Guidelines for setting up and running a pharmacovigilance

centre"[.13]

The specific aims of pharmacovigilance programmers are to:

- Contribute to the regulatory assessment of benefit, harm, effectiveness encouraging their safe, rational and effective use (including cost effective use).
- Improve patient care and in relation to use medicine and all medical and Para medical interventions.
- Improve public health and safety in relation to use of medicines
- Promote understanding, education and clinical training in pharmacovigilance and its effective communication to the public.

Future aspects of pharmacovigilance in India

With more and more clinical trials and other clinical research activities being conducted in India, there is an immense need to understand the importance of pharmacovigilance and how it impacts the life cycle of product. Given this situation, the DCGI should act quickly to improve pharmacovigilance so as to integrate good pharmacovigilance practice in to the processes and procedures to ensure regulatory compliance and enhance clinical trial safety and post marketing surveillance. A properly working pharmacovigilance system is essential if medicines are to be used safely. It will benefit all parties including health care professionals, regulatory authorities, pharmaceutical companies and the consumers. It helps pharmaceutical companies to monitor their medicines for risk and to devise and implement effective risk management plans to save their drugs in difficult circumstances.

Making pharmacovigilance reporting mandatory and introducing pharmacovigilance inspections High-level discussions with various stake holders Strengthen the DCGI office with trained scientific and medical assessors

e-ISSN: 2582-5208
International Research Journal of Modernization in Engineering Technology and Science
(Peer-Reviewed, Open Access, Fully Refereed International Journal)
Volume:06/Issue:12/December-2024 Impact Factor- 8.187 www.irjmets.com

for pharmacovigilance Creating a single country specific adverse event reporting form to be used by all Creating a clinical trial and post marketing data base for SAEs/ SUSARs / and ADRs for signal detection and access to all relevant data from various stake holders List all new drugs/ indications by maintaining a standard data base for every pharmaceutical company Education and training of medical students, pharmacists and nurses in area of pharmacovigilance.

Collaborating with Pharmacovigilance organizations in enhancing drug safety with advancements in information technology there has been the emergence of new opportunities for national and internatio[n14a]l

- Building a network of pharmacovigilance and pharmacoepidemiologists in India.

Developments

- Drug safety information must serve the health of the public.
- Education in the appropriate use of drugs, including interpretation of safety information, is essential for public at large, as well as for health care providers.
- All the evidence needed to assess and understand risks and benefits must be openly available.
- Every country needs a system with independent expertise to ensure that safety information on all available drugs is adequately collected impartially evaluated and made accessible to all.
- Innovation in drug safety monitoring needs to ensure that emerging problems are promptly recognized and efficiently deals with and that information and solutions are effectively communicated.

AIMS OF PHARMACOVIGILANCE

The aims of pharmacovigilance are

The identification of sub-groups of patients at particular risk of ADRs (the risk relating to dose, age, gender and underlying disease). The continued monitoring of a safety of a product, throughout the duration of it use, to ensure that its risks and benefits remains acceptable. This includes safety monitoring following significant newly approved indications. The comparative adverse drug reaction profile of products within the same therapeutic class. The detection of inappropriate prescription administration. The further elucidation of a product pharmacological/toxicological properties and the mechanism by which it produces adverse drug reactions. The detection of significant drug-drug interactions between new products and co-therapy with agents already established on the market, which may only be detected during widespread us[e1.5]

In short, pharmacovigilance aims to improve patient care and safety, public health, assessment of benefit, harm, effectiveness and risk of medicines promote understanding, education and clinical training.

IMPORTANCE OF PHARMACOVIGILANCE

When a pharmaceutical drug is introduced in the market there are still a lot of things that are unknown about the safety of the new drug. These medicines are used by various patients for different diseases who might be using several other drugs and must be following different traditions and diets which may adversely affect the impact of medicine in them. Also the same medicine might differ in the manner of their production and ingredients. Additionally adverse drug reactions might also occur when drugs are taken along with traditional and herbal medicines which should be monitored through pharmacovigilance. In some cases, adverse drug reactions of certain medicine might occur only in one country or region. To prevent all undue physical, mental and financial suffering of patients, pharmacovigilance proves to be an important monitoring system for the safety of medicines in a country with the support of doctors, pharmacists, nurses and other health professionals of the[1c6o]untry. The importance of pharmacovigilance is as follows.

- Safety monitoring of medicinal products
- Case reports
- Developing case series
- Analysis of case series
- Use of data mining to identify product -event combination
- Spontaneous reporting [1g6.]

e-ISSN: 2582-5208
International Research Journal of Modernization in Engineering Technology and Science
(Peer-Reviewed, Open Access, Fully Refereed International Journal)
Volume:06/Issue:12/December-2024 Impact Factor- 8.187 www.irjmets.com

STEPS IN PHARMACOVIGILANCE PROGRAMME

1. Finding the risk of a drug
2. Clinical trials
3. Pharmacoepidemiological study
4. Case report
5. Developing case series
6. Analysis of case series
7. Use of data mining to identify product- event combination
8. Spontaneous reporting.

ACTIVITIES IN PHARMACOVIGILANCE OPERATIONS

Case Registry

- Triage
- Registry
- Enrollment

Processing

- Data Entering
- Coding
- Labelling

Medical Review

- Analysis And Creation of Psur & Bridge Reports

PARTNERS IN PHARMACOVIGILANCE

A complex and vital relationship exists between wide ranges of partners in the practice of drug safety monitoring. Sustained collaboration and commitment are vital if future challenges in pharmacovigilance are to be met in order to develop and flourish.

- Government
- Industry
- Hospital and academ[1ia7]
- Poison information centers
- Health professiona[l1s8,19]
- Patients
- Consumers
- Media
- WHO

III. CONCLUSION

Pharmacovigilance is the only way to ensure the safety of the drug throughout the life cycle. It is very much crucial as the clinical trials have limitation to detect the rare and very rare ADRs. The knowledge and information available regarding safety of any drug is very much important to take appropriate decision by drug regulators to safe guard public health. Health care professionals are the main reporters of the ADRs. However there are high percentages of under-reporting reported globally. It is the major challenge of today. In spite of those limitations, spontaneous reporting system remains as a most widely used method to report ADRs and is able to generate signal of rare and very rare types of ADRs. If all the health care professionals take ADR reporting as an ethical obligation and a major responsibility, we can make our world safer than what is today. Every reporting by health care professionals is important, even though focus on the serious unlabelled types of ADRs is more important. There are significant effects on the pharmacovigilance to make it more functional after the concept has emerged and day by day we are getting closer to the destiny. It is our responsibility to ensure

well functioning of pharmacovigilance system. ADR reporting should be taken as a very important duty not as an extra clinical burden by health care professionals to ensure the safer drugs use throughout the world.

IV. REFERENCE

[1] World health organization collaborating centre for international drug monitoring (2007). The importance of pharmacovigilance available at http://www.who_umc.org cited 18 December 2007.

[2] Lazarou J, Pomeranz BH, Corey PN; Incidence of Adverse Drug Reactions in hospitalized patients. JAMA, 198; 279: 1200-1205.

[3] Bord CA, Rachi CL; Adverse Drug Reactions in United States Hospitals. Pharmacotherapy, 2006; 26(5): 601-08.

[4] World Health Organiation(WHO), Uppsala Monitoring Centre(internet). The use of WHO-UMC system for standard case causality assessment available at http://www.who- umc.org/graphics/4409.pdf.

[5] Macedo AF, Marques FB, Ribeiro CF, Texeira F. Causality assessment of adverse drug reactions: comparision of the results obtsined from published decisional algorithms and from the evaluations of an expert panel. Pharmacoepidemiological drug sof., 2005; 14: 885-890.

[6] Arimone Y, Begnad B, Miremont, Salame G, Fourrier-Regalt A, Moore N, Molimard M et al, agreement of expert judgment in causality assessment of adverse drug reactions. Eur J Clin pharmacology, 2005; 61: 169-173.

[7] Joerg H. Basic principles of pharmacovigilance and data sources.

[8] Sachdev Y. pharmacovigilance: safety matters, Indian pharmacology. February 2008; 40. Hall et al. 1995; Horbuckle et al. 1999; Tuntti and Neuroren 2002.

[9] Moore N (2001). The role of clinical pharmacologist in management of ADRs. Drug safety, 211(1): 1-7.

[10] The importance of pharmacovigilance; safety monitoring of medical products, Geneva, WHO, 2002.

[11] J.P Loannidis, J Lau. Completeness of safety reporting in randomized trials: an evaluation of seven medical areas. JAMA, 2001; 285(4): 437-443.

[12] P.Biswas, A. K. Biswas setting standards for proactive pharmacovigilance in India: the way forward. Indian Journal of pharmacology, 2007; 39: 124-128.

[13] Ronaldd M, Flizabeth BA. Moore N. The role of clinical pharmacologist in the management of ADRs. Drug safety, 2001; 24(1): 1-7.

[14] Hall M, Mc Cormack P, Aurthur N, Feely J. The spontaneous reporting of ADRs by Hornbuckle K, WUH-H, Fung MC. Evaluation of spontaneous adverse event of reports by primary reporter a 15 year review (1983-1997). Drug information journal of clinical pharmacology, 1995; 40: 173-175.

[15] Consumer reporting ADRs. WHO drug information, 2000; 14: 211-215.

[16] Egberts GPG Smulderes M, De Konig FHP et al. Can ADRs be detected earlier? A comparision of reports by patients and professionals. British Medical Journal, 1996; 313: 530-531.