Therapeutic Uses of PHARAMACOVIGILANCE

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Abstract- *Pharmacovigilance is more than spontaneous reporting alone, and the evaluation of marketed medicines is more than just pharmacovigilance. The positioning of a drug usually takes place during the years following introduction, when worldwide experience has accumulated. Originally a modest appendix of drug regulation, pharmacovigilance has become a major activity. The provision of the information needed for the evaluation of the benefits and risks of drugs is in the first place a scientific challenge. In addition, there are important ethical, logistical, legal, financial and commercial constraints. Good pharmacovigilance practice needs to be developed to ensure that data are collected and used in the right way and for the right purpose.*

Pharmacovigilance, and more generally the study of the benefits and risks of drugs, plays a major role in pharmacotherapeutic decision-making, be it individual, regional, national or international. In addition, pharmacovigilance is becoming a scientific discipline in its own right.

A variety of changes are taking place in the complex system of drug development, regulation and distribution. Pharmacovigilance should be proactive in monitoring their possible consequences. (1)(2)

I. INTRODUCTION

The purpose of this document is:

• To present the case for the importance of pharmacovigilanc
• To record its growth and potential as a significant discipline within medical science, and
• To describe its impact on patient welfare and public health.

It highlights the need for critical examination of the strengths and weaknesses of present pharmacovigilance systems in order to increase their impact. It anticipates developments necessary to meet the challenges of the next ten years. It argues that the distinctive approaches adopted by different countries in response to their individual needs should be supported and fostered. The document also highlights the importance of collaboration and communication at local, regional and international levels, to ensure pharmacovigilance delivers its full benefits.

Pharmacovigilance and all drug safety issues are relevant for everyone whose life is touched in any way by medical interventions. The document is intended for the following, wide-ranging readership: • Policy makers at all levels of healthcare, particularly those concerned with drug policy

- Staff and consultants in national drug regulatory authorities
- Healthcare practitioners including doctors, nurses and pharmacists
- Pharmaceutical industry executives and scientists
- Professional staff in national pharmacovigilance centres
- Editors of medical and scientific journals
- Health epidemiologists
- Health economists
- Professional staff of poison and drug information centres
- Health administrators
- Consumer groups and patient support groups
- Legal advisors in heaith care
- Schools of health sciences, and
- The concerned layperson. (3)

History of Pharmacovigilance

Beneficial and harmful properties of medical remedies have been known to mankind for thousands of years. In more recent times, serious adverse reactions associated with medical products resulted in the evolution of regulatory changes and an effort to discover drug safety issues as early as possible. Pharmacovigilance is the practice used by sponsors and regulatory bodies to detect harmful effects associated with medical products to identify potential risks and enable warnings to reach physicians in a timely manner. This chapter examines the evolution of pharmacovigilance and the history of regulatory actions following major drug-associated events.(4)

Definition of pharmacovigilance:- Pharmacovigilance is defined by WHO as “the science and activities related to the detection, assessment, understanding and prevention of adverse drug effects or any other possible drug-related problems” (6).

Scope of pharmacovigilance:-The scope of pharmacovigilance has grown remarkably in recent times and is now considered to include the following domains(7)

- ADRs or events
- medication errors
- counterfeit or substandard medicines
- lack of efficacy of medicines
- misuse and/or abuse of medicine

The purpose of pharmacovigilance

Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problems. Recently, its concerns have been widened to include: (4)

- herbals
- traditional and complementary medicines
- blood products
- biologicals
- medical devices
- vaccines.

PARTNERS IN PHARMACOVIGILANCE

The WHO Quality Assurance and Safety: Medicines Team:-

The Quality Assurance and Safety: Medicines team is responsible for providing guidance and support to countries on drug safety matters. The team is part of the Department of Essential Drugs and Medicines Policy, within the WHO Health Technology and Pharmaceuticals cluster(11)

The Uppsala Monitoring Centre:-

The principal function of the Uppsala Monitoring Centre is to manage the international database of ADR reports received from National Centres.(7) In 2002 this database held nearly three million case reports. The majority of national contributing centres have easy electronic access to these. the UMC has established standardized reporting by all National Centres and has facilitated communication between countries to promote rapid identification of signals.

The National Pharmacovigilance Centres:-

At present, post-marketing surveillance of medicines is mainly co-ordinated by national pharmacovigilance centres. In collaboration with the UMC the National Centres have achieved a great deal in: • collecting and analysing case reports of ADRs • distinguishing signals from background 'noise' • making regulatory decisions based on strengthened signals • alerting prescribers, manufacturers and the public to new risks of adverse reactions.

Hospitals and Academia:-

The efforts of clinical pharmacology and pharmacy departments around the world have resulted in the development of pharmacovigilance as a clinical discipline, A number of medical institutions have developed adverse reaction and medication error surveillance systems in their clinics, wards and emergency rooms. Case-control studies and other pharmacoepidemiological methods have increasingly been used to estimate the harm associated with medicines once they have been marketed.(8)

Health Professionals:-

The success or failure of any spontaneous reporting system depends on the active participation of reporters. Although limited schemes for reporting by patients have been initiated recently, health professionals have been the major providers of case reports of suspected ADRs throughout the history of pharmacovigilance.

Patients :-

Only a patient knows the actual benefit and harm of a medicine taken. Observations and reports made by a health professional will be an interpretation of a description originally provided by the patient, together with objective measurements. Some believe strongly that direct patient participation in the reporting of drug related problems will increase the efficiency of the pharmacovigilance system and compensate for some of the shortcomings of systems based on reports from health professionals only

Steps of pharmacovigilance

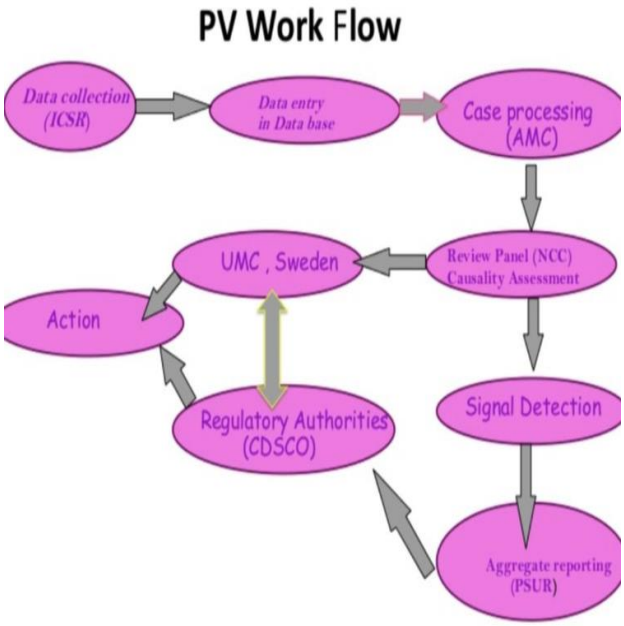

Fig 5: PV workflow

Step 1 is the collection of reports about the adverse effect and all adverse reactions of the drugs. All adverse reactions, including serious and unexpected effects, are subjected to expedited reporting.

Step 2 involves receiving the cumulative reports regarding the safety of drugs and sending those reports to all the regulatory authorities.

Step 3 The process of determining the specific adverse effect associated with a specified drug and then comparing this drug with another drug having a similar worse effect.

Step 4 Management of adverse effects of the drugs. Receive information regarding the harmful effects on patients or population and seek a method to minimize these effects.(14)

Pharmacovigilance regulations:-

International Conference of Harmonization consists of authorities from India, Europe, and Japan with representatives of the correlating industries, health organization, and WHO as an observer. This conference provides guidelines regarding **pharmacovigilance and good drugs.** There is stepwise development of instructions. At step four, there is a consensus internationally, and at step 5, an agreement for regulators to introduce the guidelines to legislation.

The principal role of pharmacovigilance is to ensure the safer usage of drugs. But the pressure is increasing on this field to analyze data about the adverse effect, monitor risk more broadly, and accurately reports patient events.(15)

II. CONCLUSION

Pharmacovigilance is essentially based on the qualitative and quantitative study of spontaneous adverse drug reaction reports,followed by a clinical assessment/judgment with regards to its impact on the overall saftty signals of arare adverse event or in orphan disease setting where exposure data are limited prior to marketing . the purpose of pharmacovigilance is to enhance patient care and patient safety in relation to the use of medicines according to the life cycle of health Product.

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