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Awareness of Pharmacovigilance

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Invited Editorial

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Pharmacovigilance (PV) department plays an important and critical role in the drug development progress. According to WHO, PV, also known as drug safety, is the pharmacological science relating to the collection, detection, assessment, monitoring, and prevention of adverse effects with pharmaceutical products. The safety of pharmaceutical product may not be well defined. When drugs are used in combination, its' post effects are generally unknown and safety concerned in different groups can be different as in young children, elderly patients and pregnant women.

Pharmacovigilance was introduced in Research and academic world with the establishment of the International Society of Pharmacoepidemiology (ISPE) in the year 1984 and of The European Society of Pharmacovigilance (ESOP – later ISOP – the International Society) in 1992, which further led to its incorporation into clinical practice. [1]

1. **Objectives of pharmacovigilance**
   - To detect the risk factors associated with drugs
   - To identify unknown safety problems
   - To quantify the probability of risk
   - To measure the effectiveness[1]
2. **The national pharmacovigilance centres**
   At present, post-marketing surveillance of medicines is mainly co-ordinated by national pharmacovigilance centres. The collaboration of National centres with the UMC (the Uppsala Monitoring Centre-The WHO Collaborating Centre for International Drug Monitoring) 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 about new risks of adverse reactions

Further, the extent of activities of the National centres has expanded including notification of information about benefit, harm, effectiveness and risk to practitioners, patients and the public. Major centres in developed countries have established active surveillance programmes using record linkage and prescription event monitoring systems (PEM) to collect epidemiological information on adverse reactions to specific drugs. Such systems have already been implemented in New Zealand, the United Kingdom, Sweden and the United States of America.

As the drug information is rapidly increasing across the world, the need for routine and rapid communication between National Centres and national regulatory authorities has also increased. Many regulatory authorities in different regions of the world have developed close ties with each other to discuss safety data obtained on particular medicines and the regulatory decisions being made in response to them.[2,3] (The importance of pharmacovigilance, safety monitoring of medicinal products, WHO 2002, Page 11)

2.1 Pharmacovigilance in different countries/ regions

Based on the WHO guidelines, all the regions of the world have their own particular Pharmacovigilance system.

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2.1.1 Pharmacovigilance in Europe

In Europe, the Pharmacovigilance system is called EUDRA vigilance, which has separate but similar database for human and veterinary adverse reactions. This system is coordinated by European Medicines Agency (EMA) and conducted by the National Competent Authorities (NCAs). The EMA maintains and develops the Pharmacovigilance database comprising all suspected serious adverse drug reaction observed in the European region. EMA Pharmacovigilance legislation regulated by Article 106 of Directive 2001/83/EC, Directive 2001/20/EC & Article 26 of Regulation (EC) No. 726/2004 EMEA& EC.[4]

2.1.2 Pharmacovigilance in United States

Here Pharmacovigilance has a multiple approach. Three branches of Pharmacovigilance in the USA have been defined by the FDA to evaluate product risks and promote the safe use of products by the American people. These three divisions / branches come under the Office of Surveillance and Epidemiology (OSE).[4]

Three Divisions within OSE:

1. Division of Drug Risk Evaluation (DDRE)
2. Division of Medication Errors and Technical Support (DMETS)
3. Division of Surveillance, Research and Communication Support (DSRCS)

2.1.3 Pharmacovigilance in India

Based on the WHO recommendations made in the document titled, "Safety monitoring of Medicinal products-guidelines for setting up and Running a Pharmacovigilance Centre", the Central Drugs Standard Control Organisation (CDSCO), ministry of health and family welfare, Govt of India launched the National Pharmacovigilance Program (NPP) in November, 2004.[4]

3. Pharmacovigilance in drug regulation

Drug regulatory systems provide the basis for, a national philosophy of drug safety and increasing the confidence of public in medicines. The drug regulatory authorities have to deal with many issues for the approval of new medicines, which includes

- clinical trials
- safety of complementary and traditional medicines, vaccines and biological medicines
- developing lines of communication between all parties with an interest in drug safety and ensuring that they are open and able to function efficiently, particularly at times of crisis.

There is need of strong linkage between PV programs and drug regulators to assure that the authorities are well concise on safety issues in everyday practice, which can have an impact on future regulatory action. Regulators are well acquainted with a unique and pivotal role of PV in ensuring ongoing safety of medicinal products. Hence, for the achievement of the PV objectives, there is need of adequate support for PV programmes.

For the approval of a new drug by the national drug regulatory authority, it must pass through three obstacles

Sufficient evidence is required to show the new drug to be

- of good quality,
- effective, and
- safe for the purpose or purposes for which it is proposed.

Whereas the first two criteria must be met before any consideration can be given to approval, the issue of safety is less certain. Safety is not absolute, and it can be judged only in relation to efficacy, requiring judgment on the part of the regulators in deciding on acceptable limits of safety. [2, 3]

3.1 Post-marketing safety monitoring

To avoid loss of important innovations in an extremely restrictive regulatory network, the process of evaluating drug safety needs to happen in the post-marketing (approval) phase. Judgment as to whether and how to evaluate data lies with the regulators.

The early release of new drugs with their therapeutic advances depends on the pharmacovigilance and ADR reporting,

the stronger the national system of pharmacovigilance and ADR reporting, there will be early release of new drugs. Legislation governing the regulatory process in most countries allows for conditions to be placed on approvals, such as a requirement that there should be detailed pharmacovigilance in the early years after a drug's release.

There are other aspects of drug safety that have been rather neglected until now but should be included in monitoring latent and long-term effects of medicines. These include:

- detection of drug interactions
- measurement of the environmental burden of medicines used in large populations
- assessment of the contribution of 'inactive' ingredients (excipients) to the safety profile
- systems for comparing safety profiles of similar medicines
- surveillance of the adverse effects on human health of drug residues in animals, e.g. antibiotics and hormones.

3.2 -International harmonization of drug regulatory requirements

In the last few decades, multinational organizations at regional and inter-regional levels harmonized the various elements of drug regulatory activities, which are being followed in all WHO regions. The increase of global trade in pharmaceutical products and the growth in complexity of technical regulations related to drug safety and quality leads to these efforts. The ICH initiative, which started in 1990, is an inter-regional attempt covering seventeen high-income countries. [2, 3]

3.3 Pharmacovigilance and the national drug regulatory authority

Pharmacovigilance has become an essential component of drug regulation. For the forthcoming future of developing countries, this is likely to take the traditional form of spontaneous monitoring, even though it is a far from perfect system. Many developing countries lack the primary fundamental systems of Pharmacovigilance. Further in some countries even though these systems do exist, there is lack of active support and participation amongst health professionals, regulators and administrators. In all countries the major issue is proper interpretation of ADRs by healthcare professionals. Hence post-marketing surveillance serves a distinct function within the national drug regulatory authority, separate from the process of evaluation and approval of new medicines. [2, 3]

(The importance of pharmacovigilance, Safety monitoring of medicinal products, WHO 2002, Chapter 4)

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