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BOOK REVIEW

The Importance Of Pharmacovigilance

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Monitoring Adverse Drug Reactions (ADR) and Pharmacovigilance (PV) are important issues today. The present booklet highlights the importance of pharmacovigilance, aims to record its growth and potential; and explores its impact on patient welfare and public health. The Thalidomide Disaster was an event that prompted member states and the World Health Organization (WHO) to address issues of drug safety. The WHO pilot research project for international drug monitoring was started in 1968. Various countries developed their own systems for reporting and collecting ADR reports.

The pilot project developed into the WHO Programme for International Drug Monitoring and is coordinated by the Uppsala Monitoring Centre (UMC) in Sweden. In many developing countries obtaining data on ADRs in their own populations through clinical trials is not necessary before marketing permission is granted for a drug. In such a situation, a PV programme can be of help to detect ADRs. Early examples of ADR monitoring and the creation of International Society of Pharmacoepidemiology (ISoP) are described. The widening scope of PV has been described in chapter 2. New safety concerns are raised about illegal sale of medicines, self-medication, sale of counterfeit and substandard medicines and use of herbal medicines. The widening scope of PV to include herbals, blood products, medical devices and vaccines has been described. The problem of medication error is also coming within the focus of PV.

The third chapter describes various partners in PV. The "WHO Quality Assurance and Safety of Medicines" team is responsible for providing support and guidance to countries on matters regarding drug safety. The Uppsala Monitoring Centre maintains an international database of ADR reports and communicates with various national centers. The Clinical Pharmacology and Pharmacy Departments play a vital role in development of PV as a discipline. Health professionals have an important role in the success or failure of spontaneous ADR reporting systems.

PV plays a vital role in drug regulation. In Nepal, the national drug regulatory authority, the Department of Drug Administration (DDA) is the national PV centre. Clinical trials done before a drug is marketed are carried out in a limited number of patients and have a number of limitations. Post-marketing surveillance and PV play a vital role in generating data on drug safety. Influence of promotional activities by the pharmaceutical industry and especially of Direct to Consumer Advertising (DTCA) on drug safety has been briefly mentioned. In developing countries, herbal and traditional medicines are widely marketed. These medicines are subject to less stringent regulatory control compared to allopathic medicines. These medicines can also cause significant adverse effects as has been previously reported. Vaccines are often administered to healthy children and may require a different modified system of PV. Vaccines are not emphasized in the PV

programs in hospitals of Nepal though ADR reports are accepted.

PV forms an important aspect of clinical practice. Drug safety monitoring is important for effective use of medicines and for the provision of high quality care. The booklet looks at how health professionals can be involved in PV programs. PV can play an important role in international health which forms the focus of the sixth chapter. ADRs exert a significant burden on public health. The Erice declaration of 1997 challenges all the players involved in PV viz. public health administration, health professionals, pharmaceutical industry, governments, drug regulators, media and the consumers to strive towards the highest ethical, professional and scientific standards in protecting and promoting safe use of medicines.

The internet has facilitated uncontrolled sale of medicines and this has rendered PV difficult. The book ends with considerations for future. Priority areas to be addressed in the areas of detection of ADRs, assessment, prevention of ADRs and communication are detailed. Glossary of terms is useful to reader and list of references is comprehensive. Use of bureaucratic and formal language throughout the book can pose a problem. The book can be more beneficial if more simple and direct language is used.

High production values characterize this handy and useful book. It should be essentially read by all those interested in and involved in PV.

About the Book

The World Health Organization. The importance of pharmacovigilance. Safety monitoring of medicinal products. 2002. ISBN 92 4 1590157