PHARMACOVIGILANCE IN ITMS

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Introduction

Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects of drugs or any other possible drug related problems.

Medicines have changed the way in which diseases are managed and controlled. However, despite all their benefits, evidence continues to mount that adverse reactions to medicines are a common, yet often preventable cause of illness, disability and even death. In some developed countries Adverse Drug Reactions (ADRs) is amongst the leading causes of mortality and hospital admissions due to ADRs is more than 10% even in some of the most developed countries. We can only suspect that situation must be worst in developing countries due to lack of legislation & proper drug regulations, including ADR reporting, large number of substandard and counterfeit products circulating in their markets, lack of independent information and the irrational use of drugs.

In addition to the cost of human lives and sufferings the suitable services to treat ADRs impose a high financial burden on health care due to the hospital care of patients with drug related problems. Some countries spend as much as 15-20% of their hospital budget dealing with drug complications.

Therefore, Pharmacovigilance is the science that has been developed to detect, assess, understand and prevent adverse effects of drugs or any other drug-related problems. A very successful and well established Pharmacovigilance system in the country can contribute to the prevention of drug-induced human sufferings and avoid financial risks associated with unexpected adverse effects.

Rationale of Pharmacovigilance in ITMS

Plants have been used for the treatment of illness in humans since prehistoric times. In recent years ADRs due to traditional herbal based medicines has been reported in various countries and particularly in developed countries where there are established Pharmacovigilance centers. An increase in rate of reports of ADRs from herbal medicines in many countries suggests that there is a need for Pharmacovigilance of traditional medicines. The Pharmacovigilance for allopathic medicines is quite well established in many countries but it is not the case with traditional medicines. Most countries are only beginning to tackle this problem including WHO-Uppsala monitoring centre due to inherent complexities attached with the traditional medicines.

Here in Bhutan, traditional medicine being an integral part of the national healthcare delivery system in our unique integrated health care system, the need for Pharmacovigilance centre for detecting and reporting of adverse reactions of traditional medicines was identified and the Pharmacovigilance centre for traditional medicines established with the Pharmaceutical and Research Unit (PRU) in 2005. The Pharmacovigilance was felt necessary for the following reasons:

i. Traditional medicines have been used for thousands of years but not well documented with regard to their ADRs.
ii. The complexity of ingredients makes it very difficult to carry out safety and toxicity studies in animals (No preclinical studies data).
iii. There are hearsay reports of some of the patients suffering of ADRs from traditional medicines.
iv. Data collected can be useful for research and development on Traditional medicines.
v. Pharmacovigilance can help in making traditional medicines safer.

Aims of Pharmacovigilance Centre for Traditional Medicines at PRU

The Pharmacovigilance centre was established with the objective of achieving the following:

i. Early detection of hitherto unknown ADRs and interactions due to traditional medicines and their interactions with allopathic drugs or other substances
ii. Identification of risk factors and possible mechanisms underlying ADRs
iii. Estimation of benefit/risk analysis and dissemination of information needed to improve drug prescribing and regulation
iv. Promoting safe and rationale use of traditional medicines
v. Assess the risks and benefits of traditional drugs and communicate to the ITMS, Drungtshos, health professionals and patients.
vi. Works towards centre of excellence for traditional medicines related Pharmacovigilance activities and research.

Conclusion

After almost two years of establishment of the centre in ITMS, the response from the traditional medicine health workers on ADRs reporting hasn't been very satisfactory but the centre is hopeful that with more aggressive awareness campaigns and advocacy, our message of the importance of reporting ADRs due to traditional medicines to the centre would get through to the traditional health workers and to the patients. The centre is of not much use without the active cooperation and participation of the traditional health workers and patients in collecting the information on ADRs due to traditional medicines. The lack of budget has been another major stumbling block for the progress of the centre but the centre will try its best to ensure that the ADRs is taken very seriously and that its activities will be reinforced for strengthening and development of traditional medicines. For the successful achievement of the aims and objectives of the centre I would like to request all health workers (traditional medicine or others) and everyone to report ADRs due to traditional medicines (confirmed or suspected) to the centre to benefit everyone.

References:

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