

## **Role of drug and therapeutics committee towards drug safety- experiences from western Nepal**

**Palaian S<sup>1</sup>, Mishra P<sup>2</sup>**

<sup>1</sup>Lecturer, <sup>2</sup>Asst. Professor, Dept. of Pharmacology and Pharmacy, Manipal College of Medical Sciences

**D**rug and Therapeutics Committee (DTC) is a policy framing and recommending body to the medical staff and the hospital administration on matters related to the therapeutic use of drugs. This committee is composed of clinicians, pharmacists, nurses and other health care professionals.<sup>1</sup>

The DTC of Manipal Teaching Hospital (MTH) was reorganized in March 2004 with the objectives of promoting safe, effective and economic use of drugs in the hospital. The committee is composed of chairman (Head of the Department, Medicine), member secretary (Chief, Pharmaceutical Services) and members (head of all clinical departments). The committee meeting is held every three months in order to discuss the issues regarding drug use in this hospital. A maximum of three brands per generic is approved by the committee for use in the hospital. The committee usually adds a list of drugs and deletes few from the list based on the recommendations of the user departments. Drugs (newer brands/generics) are approved based on their safety, efficacy, availability and cost parameters. The necessary information on drugs is provided by the Drug Information Center of the MTH. The first DTC meeting of this year was held on 16<sup>th</sup> February, 2005 and discussions were held on various issues regarding drug use in the hospital. Based on the safety data and other available reports, the DTC decided to ban all the preparations having Phenylpropanolamine (PPA) for use in the hospital. The study named *PPA and risk of hemorrhagic stroke: final report of the hemorrhagic stroke project (2000)* reported an association between PPA use and hemorrhagic stroke in women. Increased risk of hemorrhagic stroke was found for women using PPA for weight reduction and as nasal decongestant.<sup>2</sup> Depending on the safety profile, the committee also denied the approval of Nimesulide, a non-steroidal anti-inflammatory drug (NSAID) used in the treatment of certain inflammatory conditions and fever. The hepatotoxic effects of the drug have created a major concern in the recent days. There are several reports of fatal hepatotoxicity associated with the use of this drug.<sup>3</sup> Considering the possibility of hepatotoxicity due to the drug and the availability of other safer and

effective alternatives, the committee decided not to approve this drug.

The hospital DTCs should come forward to devise mechanism to report Adverse Drug Reactions (ADRs), evaluate their nature, classify them based on their severity<sup>4</sup> and should establish the causal relationship between the drug and the reaction.<sup>5</sup> Upon occurrence of ADRs, the committee should discuss it in detail and decide on the future use of the drug in the hospital. In certain cases, based on the risk versus benefit analysis, the DTC can discontinue its use in the hospital.

In developing countries like Nepal, where the pharmacovigilance programs are in its primitive stage, the DTC has immense responsibility in ensuring drug safety. This committee can also act as an advisory committee to the policy makers and drug regulatory authority of Nepal for drug safety matters based on their experiences.

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