

Sep 16 2014 : The Times of India (Kolkata)

## Generic drugs skip quality control test, govt apathetic

DurgeshNandan Jha

### **New Delhi:**

While the Indian government is pushing generic drugs as they are cheaper and, therefore, more affordable, there seems to be inadequate attention on ensuring that the quality protocol of these drugs is properly observed.

A case in point is a lifesaving drug, Liposomal Amphotericin B, which is used to treat fungal infections in critically-ill patients. Several doctors say while the need for the drug is obvious, the Drug Controller General of India (DCGI) has failed to ensure that pharmaceutical companies manufacturing the generic version of this drug carry out proper tests.

In fact, a government-appointed expert committee had recommended action against the erring pharma companies. TOI also has a copy of a letter from V M Katoch, the director general of Indian Council of Medical Research (ICMR) to the DCGI on June 4, calling for action against companies manufacturing and marketing untested Liposomal Amphotericin B.

"The quality of these preparations will immensely affect the efficacy and toxicity," the letter states. Ka toch told TOI he wrote this letter in response to complaints received by him.

When contacted, DCGI G N Singh said the matter was forwarded to the state authorities for necessary action. "I am not aware of the present status of this particular case but licenses are given for the manufacture and marketing of generic drugs after detailed examination of the risk factors," he said.

Doctors say the obvious risk of Amphotericin B is its high toxicity , which can lead to kidney failure and death. However, given that it's a lifesaving drug, used when patients are in terminal decline, they have little option but to use the generic version, especially for poor patients. Liposomal Amphotericin B was included in the Indian Pharmacopoeia the standards setting institution for drugs in India in the year 2010 and a number of licenses for the manufacture of generic versions of the same drug were granted without clinical trials. It was removed later when a senior official from the department of biotechnology raised objections. But the companies are still selling them," said one of the experts.

<b>DRUG WHOSE PATENT HAS ENDED</b>	
<b>What is a generic drug?</b>	
Copy of original drug whose patent has ended. It's sold under its generic name (chemical compound) an adopted name	
<b>What's the cost advantage?</b>	are some leading generic drug makers
Average cost of generic drug is 80-85% lower than the original. That's because there's no R&D cost involved	<b>Does lower price mean inferior quality?</b>
<b>Who makes generic drugs?</b>	No. A generic drug is the same in terms of chemical composition, dosage, safety and strength
Any drug manufacturer can make them after approval from the drug controlling authority. Cipla, Dr Reddy's and Ranbaxy	

