

**GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA**

UNSTARRED QUESTION NO:6804
ANSWERED ON:11.05.2005
PROMOTION OF LETROZOLE
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Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

- (a) whether Letrozole was promoted and marketed by M/s Sun Pharmaceutical Industries without obtaining prior permission from Drug Controller General of India and violating Drugs and Cosmetics Act, 1940;
- (b) if so, the facts thereof;
- (c) whether clinical trial of this drug in infertility cases was conducted on a large number of women; and
- (d) if so, the details thereof and the action taken/proposed to be taken by the Government in this regard ?

Answer

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH & FAMILY WELFARE (SMT. PANABAKA LAKSHMI)

(a) to (d) : The Drug Regulatory Authority had approved marketing of Letrozole by M/s. Sun Pharmaceuticals on 28th June 2001, and by a few other firms, as second line treatment of advanced Breast Cancer in women. Since, no approval was issued for its use as fertility drug, the firm was issued a notice on 25.9.2003, to explain about their alleged promotion of Lertozole as a fertility drug.

The firm explained that they did not make any, specific claim about its use in fertility on the label of their product. However, based on the articles published in International Medical Journals about beneficial use of letrozole in fertility enhancement, the gynecologists in the country have used it for their patients. The firm was however `Warned` not to engage in any promotional activity, which leads to off-label use of anti-cancer drug letrozole for fertility enhancement.

Letrozole, which was developed as inhibitor of estrogen synthesis is reported to have been used by some Gynecologists in developed countries for treatment of infertility, and such studies have been published. Reports about the drug affects on the health of women have not come to notice.

Experts consulted in the matter had opined that aromatase inhibitors like Letrozole have been used for ovulation induction and the drug is well tolerated.