

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

UNSTARRED QUESTION NO:3425
ANSWERED ON:22.12.2004
CLINICAL TRIAL OF PAROXETINE
Paraste Shri Dalpat Singh

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether a case has been filed against Glaxo for concealing the negative results of a Clinical Trial in UK and USA for their drug Paxil (Paroxetine)

(e);

(b) if so, the details and reported side effects of Paxil; and

(c) the action being taken by the DCGI in this regard for the assessment of this drug in India?

Answer

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

(a) & (b) : Reports have appeared that the New York State Attorney General has accused British Drug Company M/s. Glaxo Smith-Kline for withholding negative information and misrepresenting data about the efficacy and safety of prescribing anti-depressant drug Paxil (Paroxetine) in children. There has been concern over the increase in the suicidal tendency with the use of Paroxetine for treating depression in children under 18 years of age.

(c): The matter was examined in consultation with experts and Indian Psychiatric Society (IPS). The Society suggested that Paroxetine should be allowed to be used in the treatment of depression in children and adolescents below 18 years age but caution should be taken and these patients must be screened regularly for increase (if any) of suicidal ideation.