

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

UNSTARRED QUESTION NO:233  
ANSWERED ON:06.12.2013  
APPROVAL TO MALARIA DRUGS  
Sivasami Shri C.;Thamaraiselvan Shri R.

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

- (a) whether the Government has received a number of proposals for approval of drugs for the prevention and treatment of various diseases;
- (b) if so, the details thereof along with the number of them pending for approval indicating the reasons for the same during each of the last three years and the current year;
- (c) whether the Central Drugs Standard Control Organisation (CDSCO) has recently given approval for manufacturing and marketing of a drug for the treatment of uncomplicated malaria in adults caused by Plasmodium vivax parasite in the country;
- (d) if so, the details thereof; and
- (e) whether the CDSCO has given permission for the pediatric formulation of the said drugs, and if so, the details thereof?

**Answer**

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI GHULAM NABIAZAD)

- (a) & (b): Yes. CDSCO receives proposals on regular basis for approval of drugs for the prevention and treatment of various diseases. Guidelines and requirements for approval for new drugs are specified in Drugs and Cosmetics Rules, 1945. The evaluation of new drug applications, wherein establishing safety and efficacy of the drug in is of paramount importance, is a complex process, which varies according to the nature of molecule/drug, the published data and information furnished by the applicants. It involves examination of chemical & pharmaceutical information, animal pharmacological & toxicological data, clinical data of safety & efficacy, laboratory test report etc. Various New Drug applications are under different stages of processing in the office of the Drugs Controller General (India) like under clinical trial, bio equivalence study, laboratory testing, examination of technical document etc.
- (c) & (d): CDSCO has granted approval on 14.10.2013 for manufacturing and marketing of Fixed Dose Combination (FDC) of Arterolane Maleate (150mg) + Piperaquine Phosphate Tablet (750mg) for the treatment of acute uncomplicated malaria infection due to Plasmodium vivax in adults.
- (e): No.