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

UNSTARRED QUESTION NO:1807
ANSWERED ON:25.11.2016
Clinical Trials of Medicines
Adsul Shri Anandrao ;K. Shri Parasuraman;Munde Dr.Pritam Gopinath;Raut Shri Vinayak Bhaurao;Yadav Shri Dharmendra

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

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

(a) whether as per the existing norms, the clinical trials of medicines sold in the country is compulsory, and if so, the details thereof;

(b) whether the sale of medicines manufactured in the European countries are permitted without clinical trials and if so, the reasons therefor;

(c) whether clinical trials were conducted on human beings by the drug companies during the last three years;

(d) if so, the details thereof; and

(e) whether the Government maintains a clinical trial registry to regularize clinical trials with provisions for compensation clause and if so, the details thereof and if not, the reasons therefor?

## Answer

ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND
FAMILY WELFARE
(SHRI FAGGAN SINGH KULASTE)
(a) & (b): New drug permission is required to be obtained from CDSCO before obtaining manufacturing license or import license for manufacturing/importing for sale of any new drug in the country. In case of new drug substances approved in other countries, Phase III clinical trial is required to be conducted in the country before granting permission to manufacture or import a new drug. However, the requirement of local clinical trial can be abbreviated, deferred or omitted by the Licensing Authority in certain conditions.

(c) & (d): The number of clinical trial permissions, including for global clinical trials, granted by Central Drugs Standard Control Organization during last three years and current year is as under:-

| Year | No. of Permissions Granted |
|---|---|
| 2013 | 73 |
| 2014 | 198 |
| 2015 | 216 |
| 2016 (as on 21/11/2016) | 116 |

During last three years, pharmaceutical companies conducted clinical trials for approval of 91 new drugs including vaccines and medical devices.

(e): The clinical trial registry is maintained by the National Institute of Medical Statistics (Indian Council of Medical Research). The provision for examination of Serious Adverse Events (SAE's) occurring during clinical trials and payment of compensation by the sponsor, if the SAE is established to be related to clinical trial, has been made in the Drugs and Cosmetics Rules, 1945.