GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:3584
ANSWERED ON:11.12.2009
CLINICAL TRIALS
Patil Shri A.T. Nana

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

(a) the existing mechanism set up by the Government to monitor clinical trials in the country;

(b) whether any foreign assistance has been sought by the Government for imparting training to drugs officials and strengthening the mechanism of undertaking clinical trials of new drug in the country; and

(c) if so, the details thereof?

Answer

THE MINISTER OF STATE FOR HEALTH & FAMILY WELFARE(SHRI DINESH TRIVEDI)

(a): Clinical trials are regulated under Drugs and Cosmetics Act and Rules there under.Clinical trials are required to be carried out in accordance with requirements and guidelines specified in Rule 122DA, 122DAA, 122DB, 122E and Schedule Y of Drugs & Cosmetic Rules. Schedule Y also mandates that clinical trial is conducted as per Good Clinical Practices (GCP) Guidelines issued by Central Drugs Standard Control Organisation (CDSCO), Directorate General of Health Services, Government of India. Clinical trial can be initiated in the country only after approval from Drugs Controller General (India) {DCG(I)} and respective ethics committee. From 15th June, 2009, it has been made mandatory to register all clinical trials permitted on or after the said date at Indian Council of Medical Research (ICMR) registry at www.ctri.in before enrolling first patient in the study. Such registration will improve transparency and accountability of all stake holders involved in clinical trials.

(b) & (c): In order to increase skill and knowledge of CDSCO officials in clinical trial inspections, Government has collaborated with United States Food & Drugs Administration (US FDA). So far two CDSCO - US FDA collaborative workshops on clinical trial inspections have been conducted.