GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:1583
ANSWERED ON:15.07.2009
CLINICAL TRIALS OF DRUGS ON HUMAN BEINGS
Rao Shri Kavuri Samba Siva

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

(a) whether the Indian Council of Medical Research (ICMR) and Drug Controller General of India (DCGI) are regulating the clinical trial of drugs in the country;

(b) if so, the details thereof including the norms/guidelines for such trials;

(c) whether certain companies were detected for violating guidelines on clinical trials of drugs on human beings;

(d) if so, the details of such companies;

(e) the action taken by the Government against such companies;

(f) whether the Government proposes to enact a law to regulate clinical trials in the country;

(g) if so, the details thereof; and

(h) the time by which such law is likely to be enacted?

Answer

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI GHULAM NABI AZAD)

(a) & (b) Clinical Trials in the country are regulated by Central Drugs Standard Control Organisation (CDSCO) as per the provisions of Drugs and Cosmetics Rules. The requirements and guidelines for undertaking clinical trials are specified in Rule 122DA, 122DAA, 122DB, 122E and Schedule Y of Drugs and Cosmetics Rules. Schedule Y also mandates that clinical trial is conducted as per Good Clinical Practices (GCP) Guidelines issued by CDSCO, Directorate General of Health Services, Government of India.

(c) to (e) : M/s Wyeth Pharmaceutical Limited, vide their letter dated 20-10-2008 submitted the report of Serious Adverse Events (SAE) regarding death of a subject involved in a clinical trial of 13-valent pneumococcal conjugate vaccine in India. After review of the SAE, CDSCO suspended the clinical trial on 6.11.08 in the country. Thereafter the clinical trial site, where the above said SAE occurred, was inspected by a team constituted by CDSCO, and it revealed various Good Clinical Practices (GCP) violations. Therefore sponsor (M/s Wyeth Pharmaceutical Limited), monitor (M/s GVK Biosciences Pvt. Ltd.) and the concerned investigator were issued warning letters asking corrective actions to be taken by them to prevent such violations in future. The clinical trial remains suspended at all the twelve sites from 06.11.08 to 22.04.09. The sponsor submitted various corrective actions taken to ensure GCP compliance. CDSCO scrutinized the same and decided to revoke the suspension on 23.04.2009 from all the sites except the inspected site. Further monitor and investigator of the inspected site also submitted details of corrective action taken by them, based on which the suspension from the inspected site was also revoked on 2.06.09.

(f) to (h): Government has introduced the Drugs & Cosmetics (Amendment) Bill 2007 in the Rajya Sabha on the 21st August, 2007 in the Rajya Sabha on the 21st August, 2007, which inter alia seeks to incorporate separate regulatory provisions in the Drugs and Cosmetics Act, 1940 for clinical trials. Further, draft rules approved by Drugs Technical Advisory Board (DTAB) for registration of Clinical Research Organisation (CRO) / Sponsor undertaking clinical trials in the country have been posted on CDSCO website for public comments.