

(b) what is being done to curb unethical clinical trials in the country?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI DINESH TRIVEDI): (a) Deaths may occur during clinical trials due to various reasons. These could be disease related deaths like cancer etc or administration to critical or terminally ill patients or side-effects or unrelated causes. Such deaths are investigated for causal relationship by investigator and by Medical Monitor of sponsor. The information collated revealed that there were 132 deaths in the year 2007, 288 in the year 2008 and 308 up to August 2009.

(b) There exist adequate provisions under the Drugs & Cosmetics Act and Rules to regulate clinical trials in the country. Clinical trial are required to be carried out in accordance with requirements and guidelines specified in Rule 122DA, 122DAA, 122DB, 122E and Schedule 'Y' of Drugs & Cosmetics Rules, 1945. Schedule 'Y' also mandates that clinical trial is conducted as per Good Clinical Practices (GCP) Guidelines issued by Central Drugs Standard Control Organisation (CDSCO). Clinical trial can be initiated in the country only after approval from Drugs Controller General (India) {DCG (I)} and respective ethics committee.

Further, following steps have been being taken to tighten the regulation of clinical trials in the country;

(1) 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.

(2) The Drugs & Cosmetics (Amendment) Bill 2007 has been introduced in the Rajya Sabha to incorporate regulatory provisions for clinical trial in the Drugs and Cosmetics Act, 1940.

(3) Draft guidelines and requirements for registration of organizations conducting Clinicals trial in the country for incorporation into the Drugs and Cosmetics Rule, 1945 have been developed and approved by Drug Technical Advisory Board (DTAB).

Shortage of vaccines

4237. SHRIMATI SHOBHANA BHARTIA:

SHRI N.K. SINGH:

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

(a) whether there is a shortage of vaccines for the country's Universal Immunization Programme;

(b) if so, the details thereof and corrective measures taken or proposed to be taken by Government in this regard;

(c) whether the three vaccine production units whose licensees were suspended by the Drug Controller General of India have since commenced production; and

(d) if so, the details thereof?

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI GHULAM NABI AZAD): (a) No. There is no shortage of vaccines for the Universal Immunization Programme in the country.

(b) Not applicable in view of the reply to part (a) above.

(c) and (d) Ministry of Health & Family Welfare *vide* order dated 26.02.2010 has revoked the order suspending licenses to manufacture vaccines by Central Research Institute, Kasauli, BCG Vaccine Laboratory, Guindy and Pasteur Institute of India, Coonoor. These Institutes have also been ordered to ensure that the production line is made fully compliant with GMP standards within three years from the date of the issue of the order. Pilot production in CRI Kasauli has started.

Theft of medicines and equipments from hospitals

†4238. SHRI SATYAVRAT CHATURVEDI:

SHRI MOTILAL VORA:

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

(a) the names of Government hospitals in Delhi where incidents of theft of drugs and equipments have occurred and the value involved therein;

(b) the number of precious stolen equipments and whether any report to this effect has been registered with the police; and

(c) the arrangements being made to avoid recurrence of such incidents of theft in future?

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI GHULAM NABI AZAD): (a) and (b) Health being a State subject no such information is maintained centrally. However, in so far as the Central Government hospitals namely, Dr. Ram Manohar Lohia Hospital, Safdarjung Hospital and LHMC & Associated Hospitals are concerned the detail of items stolen is enclosed as a Statement (See below).

(c) Necessary steps have been taken for strengthening the security by deployment of additional security personnel at strategic locations and by surprise checks by the designated officers of the respective hospitals to prevent recurrence of such incidents in future.

†Original notice of the question was received in Hindi.