

### National Institute of Biologicals

3750. SHRIMATI SHOBHANA BHARTIA:  
PROF. ALKA BALRAM KSHATRIYA:

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

- (a) whether CAG has recently pointed out several discrepancies in the functioning of the National Institute of Biologicals (NIB);
- (b) if so, the facts and details thereof;
- (c) whether NIB has been found testing of biological products of Chinese drugs and issuing batch release certificates without conducting all compliance tests; and
- (d) if so, the facts thereof?

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI GHULAM NABI AZAD): (a) to (d) The CAG has pointed out *inter alia* the following discrepancies with regard to the functioning of the National Institute of Biologicals (NIB):

- (i) Lapses in Scientific activities, including the batch release certification of biologicals without testing critical parameters prescribed by Pharmacopoeia.
- (ii) Non deployment of commensurate manpower despite completion of infrastructure.
- (iii) Lapses in equipment purchase and their non/under utilization.

### Clinical trial of drugs

3751. SHRIMATI SHOBHANA BHARTIA:  
SHRI VIJAY JAWAHARLAL DARDA:

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

- (a) whether Government proposes to regulate clinical trial of drugs in the country;
- (b) if so, the details thereof including norms/guidelines for such trials;
- (c) whether Government is aware that certain drug manufacturers have been found violating norms/guidelines on clinical trials of drugs on human beings; and
- (d) if so, the facts thereof and action taken by Government thereon?

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI GHULAM NABI AZAD): (a) and (b) Clinical trials are already regulated under the Drugs and Cosmetics Act 1940 and the Drugs and Cosmetic Rules, 1945 made 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 and 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).

(c) and (d) There was a report of serious adverse events regarding death of a subject involved in a clinical trial of 13-valent pneumococcal conjugate vaccine at one of the site in the country. A team was constituted to investigate the matter. The team conducted the inspection at