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

the said site. The inspections started on 13th December 2008 and continued till 14th December 2008 revealed various Good Clinical Practices (GCP) violations. Therefore the concerned investigator, sponsor and monitor were issued warning letters asking corrective actions to be taken by them to prevent such violations in future. The clinical trial remained 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.

Government guidelines on private medical colleges

3752. SHRI SUBHASH PRASAD YADAV: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether the risk undertaking format to be taken by Government/private hospital/lab centres is in accordance with Government guidelines and approval;

(b) if so, the details of Government approval in this regard;

(c) the rights that remain safe for patients following signing of the format;

(d) the steps taken or proposed to be taken by Government to safeguard the right of patients against management and surgeon in the case of any untoward incident during or after operation; and

(e) the vital decisions taken during the last three years in the process of safeguarding the rights of patients?

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI GHULAM NABI AZAD): (a) to (e) Health is a State subject. However, in so far as the Central Government Hospitals located in Delhi are concerned, all procedures including operations/surgery are performed after obtaining the consent from patients/patient's relatives/representatives informing about the procedures and risk involved as well as the benefits of the procedures to be undertaken. Committees like Patients safety committee, Infection Control Committee and Blood Transfusion Committee are in existence, in these hospitals to monitor the safety of the patients.

Population policy

3753. SHRI RAJEEV SHUKLA: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether Government proposes to achieve the Medium Term Goals identified in the National Population Policy 2000 for the year 2010;

(b) if so, the details thereof; and

(c) if not, the reasons therefor?

†Original notice of the question was received in Hindi.