(ii) to encourage pharmaceuticals innovation research and development, the benefit of section 35(2AB) of Income Tax Act 1961 may be extended by another 5 years *i.e.*, up to 31.03.2017 and the benefit of weighted exemption under this section may be increased from 150% to 200%. Further, the coverage of this Section may be extended to expenditure incurred for "Obtaining Regulatory Approvals and Filling of Patents abroad."

Deaths due to clinical trials of drugs

2333. SHRI MAHENDRA MOHAN:
PROF. ALKA BALRAM KSHATRIYA:
SHRIMATI SHOBHANA BHARTIA:

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

(a) whether there are no laws at present to penalize and monitor pharma companies which have messed up or violated norms while conducting global clinical trials for testing drugs in India;

(b) if so, the facts and details thereof;

(c) whether several drug manufacturing companies are conducting clinical trials on humans resulting in deaths;

(d) if so, whether Government proposes to tighten regulation of clinical trials in the country; and

(e) if so, the details thereof?

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

As per Rule 122DA, no clinical trial, for a new drug shall be conducted except in accordance with the permission of the Licensing Authority defined in Rule 21(b) *i.e.* Drugs Controller General (I). Further as per Rule 122DB, if any applicant fails to comply with any of the conditions of clinical trial permission, DCG(I) can suspend or cancel the permission.

Although there is no separate penal provision under Drugs and Cosmetics Act for clinical trial related offences, manufacturer and/or distributor of drugs in contravention of any provision of Act or any Rules made there under are punishable with imprisonment under section 27(d) of the Act.

(c) Pharma companies are conducting various clinical trials in the country. Deaths may occur in some clinical trials.

(d) and (e) Yes, following steps are 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 and Cosmetics (Amendment) Bill 2007 introduced in Rajya Sabha on 21.08.2007 contains separate regulatory provisions for clinical trial.

(3) For registration of Clinical Research Organization (CRO) draft guidelines have been prepared and posted on CDSCO website for public/comments.

Loopholes in medicine regulatory system

2334. SHRIMATI SHOBHANA BHARTIA:
SHRI N.K. SINGH:
DR. JANARDHAN WAGHMARE:

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

(a) whether the National Pharmaceutical Pricing Authority (NPPA) has urged his Ministry to plug loopholes in the regulatory system that allow companies to raise medicine prices by adding ingredients not listed under the law relating to drugs and cosmetics;

(b) if so, the details thereof and the reaction of Government thereto;

(c) whether his Ministry in consultation with the drug regulator propose to take any further action in this regard; and

(d) if so, the details thereof?

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI GHULAM NABI AZAD): (a) to (d) Yes. The National Pharmaceutical Pricing Authority (NPPA) under the Department of Pharmaceuticals has brought the matter to the notice of the Ministry of Health and Family Welfare that companies are resorting to the tactics of mixing food and nutrition supplements with certain drug formulations so as to circumvent the price control mechanism. The NPPA has suggested some corrective measures to be implemented in consultation with the Drugs Consultative Committee and the Central Committee on Food Standards, which, if needed, could be appropriately incorporated in the provisions of the Drugs and Cosmetics Rules, 1945 and the Prevention of Food Adulteration Rules, 1955.

Setting up of Health Council

2335. MS. MABEL REBELLO: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state: