"Centrally Sponsored Scheme of National Mission on Medicinal Plants" being implemented by National Medicinal Plants Board, Department of Ayush. The Scheme seeks to support cultivation of prioritized medicinal plants in clusters through farmers/growers organized into self-help groups, cooperatives etc. alongwith pre and post harvest infrastructure for processing and marketing.

(c) and (d) Government has approved setting up 10 clusters during the Eleventh Plan. So far, 6 (six) clusters have been approved in the States of Kerala, Punjab, Maharashtra, Tamil Nadu, Karnataka. These clusters are being developed on PPP (Public Private Partnership) basis and State Governments are not required to provide infrastructure.

Under the Scheme of National Mission on Medicinal Plants, financial assistance is being provided for setting up of nurseries, cultivation, Post Harvest Management and marketing. Government has sanctioned action plans of the State of Andhra Pradesh, Uttarakhand, Sikkim, Rajasthan, West Bengal, Orissa, Arunachal Pradesh, Haryana, Kerala, Mizoram, Tamil Nadu, Nagaland, Madhya Pradesh, Bihar and Jharkhand at a total outlay of Rs. 80.34 crores during the year 2009-10. An area of 80,000-1,00,000 hac. is anticipated to be covered under cultivation of medicinal plants during the Eleventh Plan which is expected to translate into an additional production of 2.5 lacs tons of raw material for the AYUSH industry.

Health care spending by Government

2332. PROF. ALKA BALRAM KSHATRIYA: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether pharma industry players have pointed out that Government should scale up spending on pharma industry and also take measures conducive to research and development;

(b) if so, whether industry has urged Government to speed up pharmaceutical policy especially when PM is pro-research and pharma products did not encourage the companies to spend heavily on research and development;

(c) if so, whether they have suggested that Government should work towards monopoly free environment and increase its spending on health care from 1 per cent to at least 3 per cent; and

(d) if so, the steps and measures Government proposes to take?

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI GHULAM NABI AZAD): (a) to (d) Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers had, on the request of major pharmaceuticals associations, recommended to the Department of Revenue for inclusion of the following in the Union Budget 2009-10:—

(i) to extend the date for approval by Department of Scientific and Industrial Research (DSIR) by 10 years *i.e.* up to 31.03.2017 for obtaining 100% deduction from income tax to any Indian company carrying out scientific research and development under Section 80-IB(8A). Further, this section should not be restricted to only Indian Companies.

(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.