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3.	Kidwai Memorial Institute of Oncology, Bangalore, Karnataka
4.	Regional Cancer Institute (WIA), Adyar, Chennai, Tamil Nadu
5.	Acharya Harihar Regional Cancer Centre for Cancer Research and Treatment, Cuttack, Orissa.
6.	Regional Cancer Control Society, Shimla, Himachal Pradesh
7.	Cancer Hospital and Research Centre, Gwailor, Madhya Pradesh
8.	Dr. B.R. Ambedkar Institute-Rotary Cancer Hospital, All India Institute of Medical Sciences, New Delhi.
9.	R.S.T. Hospital and Research Centre, Nagpur, Maharashtra
10.	Pt. JNM Medical College, Raipur, Chhattisgarh
11.	Post Graduate Institute of Medical Education and Research, Chandigarh
12.	Sher-i-Kashmir Institute of Medical Sciences, Soura, Srinagar, Jammu and Kashmir
13.	Regional Institute of Medical Sciences, Imphal, Manipur
14.	Government Medical College and Associated Hospital, Bakshinagar, Jammu
15.	Regional Cancer Centre, Thiruvananthapuram, Kerala
16.	Gujarat Cancer Research Institute, Ahmedabad, Gujarat
17.	MNJ Institute of Oncology, Hyderabad, Andhra Pradesh
18.	Pondicherry Regional Cancer Society, JIPMER, Puducherry
19.	Dr. B.B. Cancer Institute, Guwahati, Assam
20.	Tata Memorial Hospital, Mumbai, Maharashtra
21.	Indira Gandhi Institute of Medical Sciences, Patna, Bihar
22.	Acharya Tulsi Regional Cancer Trust and Research Institute, Bikaner, Rajasthan
23.	Pt. B.D. Sharma Postgraduate Institute of Medical Sciences, Rohtak, Haryana
24.	Civil Hospital, Aizawal, Mizoram
25.	Sanjay Gandhi Post graduate Institute of Medical Sciences, Lucknow, Uttar Pradesh.
26.	Government Arignar Anna Memorial Cancer Hospital, Kancheepuram, Tamil Nadu
27.	Cancer Hospital, Agartala, Tripura.

**Approval of clinical trials of foreign drug regulators**

949. SHRIMATI BRINDA KARAT: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

- (a) the rationale behind permitting clinical trials approved by certain foreign drug

regulators belonging to US, Canada, UK, European Medicines Agency (EMA), Germany, Switzerland, Japan, South Africa and Australia arbitrarily categorized as "A" within two to four weeks by the Drugs Controller General India (DCGI); and

(b) what are the objective parameters of including and excluding Drug Regulatory Authorities (DRAs) in Category A?

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI GHULAM NABI AZAD): (a) and (b) Requirements and guidelines for clinical trials are specified in Schedule Y of Drugs and Cosmetics Rules 1945. Clinical trials are permitted in the country as per Rule 122DA, 122DAA, 122DB, 122E of Schedule Y of Drugs and Cosmetics Rules 1945. Further, Schedule Y to Drugs and Cosmetics Rules 1945 mandates that clinical trial should be conducted as per Good Clinical Practices (GCP) Guidelines issued by the Directorate General of Health Services, Ministry of Health and Family Welfare Government of India. Clinical trials in country are not permitted arbitrarily based on the category "A" and "B".

#### **Preventing use of spurious and adulterated drugs**

950. SHRI RAJKUMAR DHOOT: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether it is a fact that many units manufacturing spurious and adulterated drugs and medicines of popular brands have been unearthed since 1 January, 2009 in different parts of the country;

(b) if so, the details thereof and the actions, taken against the culprits;

(c) whether Government would publicise details of such drugs and medicines with their source of supply for information of hospitals, chemists and general public to prevent their use; and

(d) if not, the reasons therefor?

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI GHULAM NABI AZAD): (a) and (b) The information as furnished by the State Drugs Controllers in respect of spurious and adulterated drugs detected in their States during the year 2009-10 is given in the Statement (See below).

(c) and (d) The manufacture and sale of spurious drugs is a clandestine and localized activity indulged in by anti social elements. A recent survey carried out by Central Drugs Standards Control Organisation (CDSCO) on the basis of the statistical principles provided by Indian Statistical Institute (ISI), Hyderabad to assess more extent of spurious drugs in the country has revealed that the extent of spurious drugs is about 0.045%. As the label of spurious drugs indicate the name and particulars of the genuine formulations duplicated by the manufacturers of spurious drugs, wide circulation of the particulars may result in creating unnecessary scare about the quality of genuine formulations otherwise available in the market.