1	2	3	4	5	6	7
10	Jammu and Kashmir	397	750	881	*	*
11	Jharkhand	330	330	392	*	*
12	Karnataka	2310	2310	2089	221	221
13	Kerala	809	1204	1122	82	*
14	Madhya Pradesh	1156	1238	814	424	342
15	Maharashtra	1809	3618	2292	1326	*
16	Manipur	80	240	192	48	*
17	Meghalaya	109	127	104	23	5
18	Mizoram##	57	57	37	20	20
19	Nagaland	126	NA	101	NA	25
20	Odisha	1228	725	525	200	703
21	Punjab	446	487	487	0	*
22	Rajasthan	1517	1478	1472	6	45
23	Sikkim	24	48	39	9	*
24	Tamil Nadu	1204	2326	1704	622	*
25	Tripura	79	NA	119	NA	*
26	Uttarakhand	239	299	234	65	5
27	Uttar Pradesh#	3692	4509	2861	1648	831
28	West Bengal	909	1807	1006	801	*
29	A and N Islands	19	40	28	12	*
30	Chandigarh	0	0	0	0	0
31	D and N Haveli	6	6	6	0	0
32	Daman and Diu	3	3	5	*	*
33	Delhi##	8	22	19	3	*
34	Lakshadweep	4	4	10	*	*
35	Puducherry	24	37	37	0	*
	All India[2]	23887	30051	26329	7246	2866

Notes:

\# Data for 2010 repeated

\## Sanctioned data for 2010 used

NA: Not Available

\+ Allopathic Doctors

* Surplus All India figures for Vacancy and Shortfall are the totals of State-wise Vacancy and Shortfall ignoring surplus in same States UTs

1 One per each Primary Health Centre

2 For concluding the overall percentages of vacancy and shortfall the States UTs for which manpower position is not available may be excluded.

Unauthorised drug trials

4281. SHRI NANDI YELLAIAH : Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) the details of unauthorized medical clinical drug trials having been conducted in Andhra Pradesh, district-wise during the periods 2009-10, 2010-11 and 2011-12;

(b) the details of action taken, so far, with regard to unauthorized medical clinical drug trials having been conducted in Andhra Pradesh during the aforementioned period; and

(c) the details of action taken and proposed to be taken to put an end to such unauthorised medical clinical trials in Andhra Pradesh and in various other States?

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI GHULAM NABI AZAD) : (a) to (c) There are no reports of unauthorized clinical drug trials (*i.e.* without due permission) conducted in Andhra Pradesh. There have, however, been media reports about irregularities in the conduct of clinical trials, in Andhra Pradesh as well as in other parts of the country. A Statement containing the details of cases investigated in Andhra Pradesh and action taken thereon during 2010 and 2011 is given in Statement. (*See* below) The Government has taken various steps to strengthen the regulation and monitoring of clinical trials in the country, which are as follows:

(i) All clinical trials, the permissions for which have been granted by the office of DCG(I) on or after 15 June 2009, have to be mandatorily registered on the clinical trial registry at *www.ctri.in* of Indian Council of Medical Research (ICMR).

(ii) CDSCO has issued guidelines for conducting inspection of clinical trial sites and Sponsor / Clinical Research Organisations (CROs).

(iii) Twelve New Drug Advisory Committees (NDACs) and Six Medical Device Advisory Committees (MDACs) have been constituted to evaluate clinical trials proposals. These committees consist of leading experts from Central and State Government medical institutions.

(iv) A draft notification has been issued for incorporation of a new rule in the Drugs & Cosmetics Rules, 1945, which provides the following:

- medical treatment and financial compensation to the trial subjects in case of trial related injury or death;
- Procedure for payment of financial compensation;

- Enhancement of responsibilities of Ethics Committee (EC), Sponsor & Investigator to ensure that financial compensation as well as medical care is provided to the trial subjects who suffer trial related injury or deaths and such information is provided to DCG(I).
- Amendment of the format for obtaining informed consent of trial subjects to include the details of address, occupation, annual income of the subject so as to have information regarding socio-economic status of the trial subjects.

Statement

Details of cases investigated in Andhra Pradesh and Action taken thereon during 2010 and 2011

Sl. No.	Year	Name of Firm	Name of Site	Drug	Action Taken
1	2	3	4	5	6
1	2010	Path (in Colloboration with ICMR), A-9, Qutab Institutional Area, USO Road, New Delhi-110067, India.	1. Khamamam District, Andhra Pradesh, 2. Vadodara District, Gujarat	Human Papilloma Virus Vaccine (HPV Vaccine)	This was a Phase-IV post licensure Clinical trial. The trial was initiated by PATH (Programme for Appropriate Technology in Health), an NGO. The Indian Council of Medical Research (ICMR) and the State Governments of Andhra Pradesh & Gujarat were the collaborating partners. 14091 girls received the vaccine in Andhra Pradesh whereas 10686 girls received the vaccine in Gujarat. Media reported death of 7 girls during the trial. The trial was suspended by ICMR on 7th April 2010. A Committee was appointed to enquire into "Alleged irregularities in the conduct of studies using Human Papilloma Virus Vaccine by Path in India" reported certain discrepancies in the conduct of the trial. The PATH submitted clarifications in respect of irregularities observed in the conduct of trial which is under examination. However, the trial is still under suspension.

1	2	3	4	5	6
2.	2011	Axis Clinical Limited, Andhra Pradesh	Axis Clinical Limited (Unit No. 1) 1st, 2nd, 3rd, 5th and 6th Floor, H.O. 1-1211/1, Sy. No. 66 (Part) & 67 (Part), Miyapur, Hyderabad-500050 & (Unit No. 2) Plot No. 33 to 35, Mirra Hospital, 1st Floor, Alluri Seetara-mraju Colony, Opp. JPN Colony, Miyapur, Hyderabad.	Bioavail-ability & Bio-equivalent studies of Anti Cancer Drugs (Exemistane 25mg Tablets)	M/s Axis Clinical Research, Hyderabad was reported to have conducted clinical trial of an anticancer drug on poor people without proper informed consent. The investigations revealed that the firm conducted bioequivalence study on an already approved anticancer drug and there were certain irregularities with respect to informed consent process, review and decision making process of Ethics Committee. The permission granted to the firm for conducting bioequivalence and bioavailability study was suspended on 22.06.2011. Consequent to this, the firm, on 04.07.2011, has submitted corrective actions being taken by them including revised Standard Operative Procedures (SOP's) for subject recruitment process, informed consent process, review and decision making process of the Ethics Committee. Based on further investigations and verifications, M/s Axis Clinical Research, Hyderabad was granted 'NOC' to conduct Bio-equivalence study subject to fulfillment of various condition regarding Informed Consent Process including documentation of the Informed consent process through Audio-Video means, functioning of Ethics Committee and investigators.

Shifting of NPPA under the health ministry

4282. SHRI TARIQ ANWAR : Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether it is a fact that there are many medicines on which manufacturers earn huge profits;

(b) if so, the details thereof;

(c) whether Government is planning to shift the National Pharmaceutical Pricing Authority (NPPA) to the Union Health Ministry; and