

(b) the number of cases in which legal permission has been taken for clinical trial and the number of cases that have come to the light in which permission had not been taken and number of deaths during clinical trials in the last three years;

(c) whether it is a fact that clinical trials are being carried out in the country, keeping in view the interests of multinational companies; and

(d) the number of persons died during clinical trials in the country and in whose case compensation has been paid?

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI GHULAM NABI AZAD): (a) Yes.

(b) The number of clinical trials permitted by the office Drugs Controller General (India) [DCG (I)] in the last three years *viz.* 2009, 2010 and 2011 were 453, 505 and 271 respectively. During the last three years, two cases have been detected pertaining to the conduct of clinical trial without the permission from the office of DCG (I). As per available data, the number of Serious Adverse Events of deaths in all clinical trials reported during the last three years *viz.* 2009, 2010 and 2011, were 637, 668 and 438 respectively.

(c) Clinical trials are permitted by the office of DCG (I) in accordance with the provisions of the Drugs and Cosmetics Rules keeping in view the interests of all Stake holders, irrespective of the status or interest of the applicant company.

(d) The Serious adverse events (SAE_s) of deaths may occur during clinical trials due to various reasons. These could be disease related deaths like cancer etc. or administration to critical or terminally ill patients or side-effects or unrelated causes. Such deaths are investigated for causal relationship by investigator and by the medical experts of sponsor. As per available data, the number of Serious Adverse Events of deaths in all clinical trials reported during the last three years *viz.* 2009, 2010 and 2011, were 637, 668 and 438 respectively. In 22 cases of trial related deaths in 2010, compensation has been paid by the Sponsors/Clinical Research Organizations.

Restructuring of National Mental Health Programme

103. SHRI N.K. SINGH : Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether it is a fact that a large number of people in the country are suffering from mental disorders;

(b) if so, the details thereof along with the number of such patients reported during the current year;

(c) whether Government proposes to restructure and expand the National Mental Health Programme (NMHP) across the country;

(d) if so, the details thereof;

(e) whether the World Health Organisation (WHO) has proposed some measures to bridge the gap between the availability and requirement of mental health care services in the country; and

(f) if so, the details thereof along with the follow up action taken thereon?

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI GHULAM NABI AZAD): (a) and (b) Health being a State Subject, the details of the number of patients suffering from mental disorders year-wise is not maintained centrally. Epidemiological studies from various parts of the country indicate that the prevalence of mental disorders is 6-7%. The State/ UT wise details of persons with mental illness as per 58th round (2002) report of National Sample Survey is given in Statement (*See below*)

(c) and (d) To address the huge burden of mental disorders, Government of India is implementing (NMHP) since 1982. A total of 123 districts in 30 states/UTs have been covered under the District Mental Health Programme (DMHP). There is no proposal to expand the programme beyond 123 districts in the Eleventh Five year plan. Under the Eleventh Five Year Plan, the NMHP has been restructured to include the following components:

- (i) Centres of Excellence in Mental Health and Establishment of PG training departments in mental health specialties to increase the PG training capacity in mental health as well as improving the tertiary care treatment facility in mental health with the objective to address the shortage of mental health professionals in the country. Eleven Institutes have been funded under the Centre of Excellence Scheme and 11 institutes have been funded for establishment of 27 PG training departments in mental health specialties.
- (ii) DMHP has been re-strategized during the Eleventh Five Year Plan and is being implemented in 123 districts of the country with added components of suicide prevention services, work place stress management, life skills training and counselling in schools and colleges and include Public Private Partnerships for reaching out and providing services to the mentally ill persons.
- (iii) In addition, the NMHP includes schemes for upgradation of Psychiatry wings of Govt. General Hospitals/Medical Colleges, modernization of Govt. Mental Hospitals, support for Central/ State Mental Health Authorities, Monitoring and Evaluation, Research and Training, Information, Education and Communication activities.

(e) and (f) No.

Statement									
<i>Number of persons with mental illness per 100,000 persons for each sex and State/UTs as per NSSO survey of 2002</i>									
State/UT	Rural			Urban			Rural+Urban		
	Male	Female	Persons	Male	Female	Persons	Male	Female	Persons
1	2	3	4	5	6	7	8	9	10
Jammu and Kashmir	216	137	177	169	66	119	206	123	165
Himachal Pradesh	294	126	207	133	36	83	278	117	195
Punjab	101	81	92	84	82	83	95	82	89
Chandigarh	90	0	54	57	71	62	60	63	61
Uttaranchal	157	48	106	65	101	83	136	61	101
Haryana	105	77	91	86	61	74	100	73	87
Delhi	50	32	42	28	37	32	34	36	35
Rajasthan	104	64	84	89	53	71	100	61	81
Uttar Pradesh	122	72	98	106	75	92	118	73	97
Bihar	145	62	105	105	92	99	141	66	105
Sikkim	173	95	136	63	24	45	162	87	126
Arunachal Pradesh	369	11	193	17	0	9	316	9	167
Nagaland	60	70	65	30	55	42	51	65	58
Manipur	133	101	117	154	127	140	138	108	123
Mizoram	179	138	160	155	82	115	170	112	141

Written Answers to

[13 MAR. 2012]

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Tripura	42	31	37	110	62	86	50	34	42	Written Answers to [RAJYA SABHA]
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Assam	136	74	108	81	92	87	132	75	106	
West Bengal	224	112	171	190	134	163	216	117	169	
Jharkhand	111	60	86	79	51	65	105	59	82	
Orissa	182	168	175	169	97	134	180	160	170	
Chhattisgarh	64	130	97	113	84	99	72	123	97	
Madhya Pradesh	105	93	99	125	61	95	110	85	98	
Gujarat	126	102	114	122	57	91	125	86	106	
Daman and Diu	13	42	24	121	23	76	51	34	44	
Dadra and Nagar Haveli	84	55	70	19	21	20	75	50	63	
Maharashtra	108	92	100	89	55	73	100	78	90	
Andhra Pradesh	70	78	74	69	43	56	70	68	69	
Karnataka	54	49	51	61	35	48	56	45	50	
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Andman and Nicobar Islands	203	308	258	109	53	84	175	246	211	
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