

Harmful treatment for women in cancer cases

†2704. SHRI KAPTAN SINGH SOLANKI: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether it is a fact that regular screening of chemotherapy and radiation, used for the treatment of cancer, may be harmful to women; and

(b) if so, whether Ministry has any plan to aware the public in this regard and whether there is any alternative to it?

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI GHULAM NABI AZAD): (a) Yes, the patients including women who are exposed to chemotherapy and/or radiation for the treatment of cancer are at risk for developing toxic/harmful effects.

(b) Each patient including women, are explained by treating doctor in advance, about different toxic/harmful effects which a patient may develop following the treatment with chemotherapy and/or radiation.

There are several diagnosis tests which can be used for detecting cancer. The self breast examination and clinical examination of breast are used under the National Programme for Prevention and Control of Cancer, Diabetes, Cardiovascular Diseases and Stroke (NPCDCS).

Health is a State subject and Government of India's efforts are supplement to State Government efforts.

For public awareness, a half an hour dedicated health magazine programme, Swasth Bharat/Arogya Bharatam is telecast through 30 regional Doordarshan Kendras and broadcast through 29 regional radio stations across the country. These programmes are telecast/broadcast for 05 days a week in regional languages covering all the issues relating to health care and national disease control programme.

Deaths during clinical trials

2705. SHRI DEVENDER GOUD T.: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

†Original notice of the question was received in Hindi.

- (a) the details of each of deaths taken place during clinical trials in the country during the last three years, year-wise and company-wise;
- (b) the details of compensation paid to the kith and kin of each of the trial victims in the last three years, year-wise and company-wise;
- (c) what globally harmonized standards are being followed in payment of compensation if there is death during clinical trials;
- (d) if so, whether these global standards are followed in the country in true spirit; and
- (e) if not, how the Ministry is planning to make the pharma companies, both domestic and foreign to follow suit?

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI GHULAM NABI AZAD): (a) Details of number of Serious Adverse Events of deaths in clinical trials in the country reported during the last three years and company-wise, as per the information available, is given in the Statement-I (See below).

(b) Details of cases where compensation has already been paid by the sponsors, as per the information available, during last three years in cases of deaths related to clinical trials is given in the Statement-II (See below).

(c) to (e) Clinical trials of new drugs are regulated under the Drugs and Cosmetic Act, 1940 and the Drugs and Cosmetic Rules, 1945 made thereunder. The requirements and guidelines for undertaking clinical trials are specified in Schedule Y of these Rules, which mandates that clinical trial is conducted as per Good Clinical Practices (GCP) Guidelines issued by Central Drugs Standard Control Organisation (CDSCO). The GCP guidelines have been evolved with consideration of International conference on harmonization (ICH), WHO, USFDA and European guidelines.

At present, there is no provision under these Rules requiring payment of financial compensation in case of clinical trial related injury or death of trial subject. However, Para 2.4.7 of the Good Clinical Practice (GCP) guidelines for clinical trials provides that trial participants who suffer physical injuries as a result of their participation in clinical trials are entitled to financial or other assistances to compensate them equitably for any temporary or permanent impairment or disability, subject to confirmation from Ethics Committee. In case of death, their dependents are entitled to compensation.

Draft Rules have, however, already been published for incorporating provision in the Drugs and Cosmetic Rules, 1945 for payment of financial compensation to the trial participants or his/her legal heir in case of trial related injury or death.

Statement-I

Number of deaths during clinical trials during the last three years

2009

Total Cases 637

Sl. No	Sponsor/CRO's	Sl. No	Sponsor/CRO's
1	Abott	20	J & J
2	Actelion	21	Johnson & Johnson
3	Allergan	22	Lambda
4	Amgen	23	Lilly
5	Bayer Health	24	Medpace
6	BMS	25	Merck
7	Cadila	26	MSD
8	Catalyst	27	National Aids Research
9	Chiltern	28	Nicholas
10	Cipla	29	Novartis
11	Clinigene	30	Omnicare
12	CliniRx	31	Parexel
13	Diagnoasearch	32	Pfizer
14	DNDi India	33	Pharmaleaf
15	Eisai	34	Pharmalink
16	Fulford	35	Piramal Lifesciences
17	GSK	36	PPD
18	ICON	37	PRA
19	IPCA	38	Quintiles

Sl. No	Sponsor/CRO's	Sl. No	Sponsor/CRO's
39	Reliance	45	Siro
40	Roche	46	Spectrum
41	sandoz	47	Sristek
42	Sanofi	48	Takeda
43	Schering Plough	49	Veeda
44	Serdia	50	Wyeth

2010

Total Cases 668

Sl. No	Sponsor/CRO's	Sl. No	Sponsor/CRO's
1	Acetlion	16	ICON
2	Acunova	17	Intas
3	Allergan	18	Invida
4	Amgen	19	J & J
5	AstraZeneca	20	Jubilant Clinsys
6	Bayer	21	Kemin
7	Boehringer	22	Lilly
8	Bristol Myers	23	Max neeman
9	Chiltern	24	Maya Clinicals
10	Clinigene	25	Merck
11	CliniRx	26	MSD
12	DiagnoSearch	27	Novartis
13	Dr Reddy	28	Parexel
14	GSK	29	Pfizer
15	GVK Bio	30	Pharm-Olam
		31	Piramal

Sl. No	Sponsor/CRO's	Sl. No	Sponsor/CRO's
32	PPD	39	Spectrum
33	PRA	40	Takeda
34	Quintiles	41	Torrent
35	Reliance	42	Veeda
36	Sanofi	43	Virchow
37	Serdia	44	Wyeth
38	SIRO		

2011**Total Cases 438**

Sl. No.	Sponsor/CRO's
1	2
1	Abbott India Limited
2	Actelion Pharmaceuticals Ltd, Switzerland
3	Amgen Technology
4	Apothecaries Pvt. Ltd.
5	Bayer
6	Bharat Serums and Vaccines Ltd.
7	Boehringer Ingelheim India Pvt. Ltd.
8	Bristol-Myers Squib India Pvt. Limited
9	Cadila Pharmaceuticals
10	Catalyst Clinical
11	CD Pharma
12	Daiichi Sankyo Inc.
13	Dr. Reddys Lab Ltd.
14	Ell Lilly & Company

1	2
15	Excel Life Science
16	Fresenius Kabi
17	George Institute
18	Glaxosmithkline Pharmaceuticals
19	Icon Clinical
20	Imperial Clinical
21	Incyk Bio
22	Intas Pharmaceuticals
23	Invida India Private
24	Ipsen Pharma
25	J & J
26	Jane Field
27	Jubilant Clinsys
28	Kendle Data And Technologies
29	Lambda Therapeutic
30	LG Life Sciences
31	Manipal Acunova
32	Max Neeman International
33	Merck Specialities
34	MSD Pharmaceuticals
35	National Aids Research Institute, Pune
36	NIMR
37	Novartis Healthcare
38	Panacea Biotec
39	Parexel International
40	Pat Pharma

1	2
41	Pfizer Ltd
42	Pharmanet Clinical
43	Piramal Life
44	PPD Pharmaceutical
45	PRA International
46	Quintiles
47	Reliance Life Science
48	Sanofi-Synthelabo
49	Siro Clinpharm
50	Spectrum Clinical
51	Sristek
52	St. John National Academy of Health Sciences
53	Sun Pharma
54	The George Institute
55	Trident Clinical Research
56	United Therapeutics
57	Veeda Clinical Research
58	Virchow Biotech

*(A) Details of compensations paid in the cases of
clinical trial related deaths in 2009*

Sl.No.	Sponsor	Compensation
1.	M/s. Quintiles Research India Pvt. Ltd.	Rs 1,50,000/-
2.	M/s. Roche Products (I) Pvt. Ltd., Mumbai	Rs 1,00,000/-

*(B) Details of compensations paid in the cases
of clinical trial related deaths in 2010*

Sl. No	Sponsor	Compensation
1	2	3
1	Merck	Rs 1,50,000/-
2	Wyeth	Rs 1,50,000/-

1	2	3
3	Quintiles	Rs 20,00,000/-
4	Quintiles	Rs 3,00,000/-
5	Lilly	Rs 1,08,000/-
6	Lilly	Rs 2,00,000/-
7	Lilly	Rs 2,00,000/-
8	Bayer	Rs 2,50,000/-
9	Bayer	Rs 2,50,000/-
10	Bayer	Rs 3,50,000/-
11	Bayer	Rs 2,50,000/-
12	Bayer	Rs 2,50,000/-
13	Amgen	Rs 1,50,000/-
14	Amgen	Rs 1,50,000/-
15	Bristol Myers	Rs 2,50,000/-
16	Sanofi	Rs 1,50,000/-*
17	Sanofi	Rs 1,50,000/-
18	Sanofi	Rs 2,00,000/-
19	PPD	Rs 10,00,000/-
20	Pfizer	Rs 1,50,000/-
21	Pfizer	Rs 2,25,000/-
22	Pfizer	Rs 1,50,000/-

* Compensation remained unpaid as whereabouts of the legal heir could not be located by the investigator and his team in spite of their best efforts.

*(C) Details of compensations paid in the cases of
clinical trial related deaths in 2011*

Sl. No.	Name of Sponsor/CRO	Compensation Paid
1	2	3
1	Apothecaries	2.16 lakhs
2	Fresenius	50,000
3	Fresenius	50,000

1	2	3
4	Icon	2.025 lakhs
5	Icon	2.7 lakhs
6	Icon	1.8 lakh
7	Lambda	2 lakh
8	Pfizer	1.5 lakh
9	Pfizer	5 Lakh
10	Sanofi	1 lakh
11	Sun Pharma	3 lakh
12	Sun Pharma	3 lakh
13	Sun Pharma	3 lakh
14	Sun Pharma	3 lakh
15	Sun Pharma	3 lakh
16	Veeda	50,000

Treatment of poor patients by top hospitals

2706. SHRI MOHAMMED ADEEB: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

- (a) whether it is a fact that most of the top hospitals in the country are avoiding poor patients in providing them medical services;
- (b) if so, the details thereof; and
- (c) the action being taken against them?

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI GHULAM NABI AZAD): (a) to (c) Since, the Public Health is a State Subject, no such information is maintained centrally.

However, as informed by the Government of NCT of Delhi, out of the 43 identified private hospitals presently providing free treatment to the eligible category of economically weaker section patients, the achievements of 34 identified private hospitals were either less than 10% in IPD and/or 25% in OPD. These