

treatment of cancer patients including children suffering from cancer. Further, Government of India has launched a comprehensive National Programme for Prevention and Control of Cancer, Diabetes, Cardiovascular Diseases & Stroke (NPCDCS) in 2010 in 100 districts across 21 States to support the State Governments in detection, treatment and management of cancer cases.

#### **Statement**

*Details of Blood cancer cases (Leukaemias) among children (0-14; years) by different registries - (2006-08) - Pooled*

Registry	Muultiple Leuk (C90)	Lymphoid Leuk (C91)	Myeloid Leuk (C92-94)	Leukemia Uns (C95)	Total	Total childhood cancer cases	%
Bangalore	0	61	12	21	94	236	39.8
Mumbai	3	205	51	62	321	765	42.0
Chennai	0	110	31	9	150	398	37.7
Delhi	3	331	74	52	460	1123	41.0
Bhopal	0	30	5	2	37	132	28.0
TOTAL:	6	737	173	146	1062	2654	40.0

Source: PBCR Report (2006-08) of National Cancer Registry Programme(MCRP).

#### **Granting of approval to DEANXIT**

3191. SHRI DEVENDER GOUD T.: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) when approval was granted for Fixed Dose Combinations (FDCs) of Deanxit (combination of Flupenthixol and Melitraven);

(b) the details of regulatory processes followed for approval of this drug by Central Drugs Standard Control Organisation (CDSCO);

(c) whether it is a fact that as per Indian law, every FDCs are new drugs and have to undergo all phases of clinical trials;

(d) if so, the basis on which the said drug was approved when Melitraven is not approved by India earlier;

(e) whether it is a fact that in case a drug is prohibited for sale in the country of its origin, Indian laws also prohibit the sale of the same in the country; and

(f) if so, the basis on which Deanxit has been permitted to be sold in India?

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI GHULAM NABI AZAD): (a) to (d) The FDCs falling under the purview of the definition of the term "New Drug" under Rule 122E of Drugs and Cosmetics Rules, 1945 are only considered as New drugs. The requirements for the approval of FDCs are prescribed under Appendix VI of Schedule Y of Drugs and Cosmetics Rules 1945, according to which every FDC is not required to undergo all phases of clinical trials. The available records in the office of the Drugs Controller General (India) [DCG(I)] reveal that the concerned manufacturing firm was asked *vide* letter dated 20.6.1997 to conduct clinical trial before grant of the permission.

As per the available information, the FDC of Flupenthixol with Melitracen was already approved in other countries *viz* Austria, Italy, China, Luxembourg, Switzerland, Singapore, Jordan *etc.* at the time of approval. As per the letter of Dr. Udayan Kasthigar, the then Psychiatrist, Lady Hardinge Medical College, Delhi, a report was submitted on the open study of safety and efficacy of FDC of Flupenthixol 0.5mg with Melitracen 10mg in major depressive disorders on 10.08.1998 to the then DCG(I). Dr. Kasthigar mentioned that FDC of Flupenthixol 0.5mg with Melitracen 10mg in an initial loading dose of 2 tablets daily for one week followed by a maintenance dose of 1 tablet daily for three weeks was quite effective in mild to moderate depressed patients. The approval for FDC of Flupenthixol with Melitracen (Deanexit) was granted on 28.10.1998.

(e) There is no provision in Indian laws, prohibiting the sale of a drug in the country on the basis of prohibition of sale in the country of origin.

(f) Does not arise.

#### **Fleeing of nurses by recruitment agencies**

3192.DR. V. MAITREYAN: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state: