

(iii) Whenever necessary newer technologies for manufacture of these drugs are allowed to be imported.

(iv) Installed capacity as on 4.9.1980 is being recognised (subject to certain conditions).

(v) In April, 1982 a scheme has been announced whereby the drug companies can get higher capacities re-endorsed to the extent of highest production in the 5 years ending 1981-82 plus 1/3rd thereof subject to certain conditions.

#### Experiment of New Drug for Hypertension

648. SHRI SURESH SHAMRAO KALMADI: Will the Minister of PETROLEUM, CHEMICALS AND FERTILIZERS be pleased to state:

(a) whether it is a fact that a multinational firm sought the permission of the Drug Controller to conduct human trials for a new drug HL-725 hypertension;

(b) if so, what are the views of the Drug Controlling authorities on this experiment; and

(c) whether the same drug was tested by the advanced western countries, if so, with what results?

THE MINISTER OF RAILWAYS (SHRI P. C. SETHI): (a) Yes, sir.

(b) After examining the pre-clinical data including details of pharmacological, biochemical and toxicological studies carried out with the drug submitted by the firm and also the results of the step up tolerance studies conducted with the drug in human beings to Germany, as submitted by the firm, the Drug Controller (I) had in February '82 conveyed his objection to the firm conducting clinical studies (tolerance studies in healthy human volunteers), with the new drug in hospitalized volunteers after obtaining

their prior written consent. The results of the studies conducted so far have been found to be encouraging.

(c) The studies conducted in Germany had shown good tolerance in human beings upto a dose of 500 micrograms.

#### Import of Banned Drug Amidopyrin

649. SHRI SURESH SHAMRAO KALMADI: Will the Minister of PETROLEUM, CHEMICALS AND FERTILIZERS be pleased to state:

(a) whether it is a fact that Amidopyrin a very toxic drug which has been banned in almost all the advanced countries, is being imported by India;

(b) whether the Drug Controlling authorities consider it safe for us in our country; and

(c) if so, what are the reasons therefore?

THE MINISTER OF RAILWAYS (SHRI P. C. SETHI): (a) to (c) According to available information, only Japan, West Germany and Switzerland had decided withdrawal of Amidopyrin from their Markets. In consultation with Medical Experts it was decided in December, 1978 that the import of the Drug through State Trading Corporation should be stopped, and Indian Drugs and Pharmaceuticals Ltd. should be asked to gradually stop production of the drug. The Manufacturers Associations were also informed of the decision taken by Government to phase out the use of Amidopyrin.

All the State Drug Authorities have again been told in February, 1982 to direct the firms, if any manufacturing preparations containing Amidopyrin to discontinue the same forthwith.

Amidopyrin has been included in Appendix 4 (Absolute Banned list) in