

dustry from the clutches of multi-nationals; and

(c) If so, what progress has been made in this direction?

THE MINISTER OF RAILWAYS (SHRI P. C. SETHI): (a) No, Sir.

(b) and (c) Steps taken by Government as part of the Drug Policy, to channelise the activities of foreign drug companies in accordance with national priorities, apart from reduction of their foreign equity under the Foreign Exchange Regulation Act, are indicated below:

(i) Foreign companies are eligible for industrial licences only for bulk drugs from the basic stage involving high technology and intermediates therefor.

(ii) No foreign drug company is eligible for industrial licence for drug formulations not linked with manufacture of bulk drugs of high technology from basic stages.

(iii) List of bulk drug which are open to (a) Public Sector (b) Indian Public Sector and (c) all Sectors have been drawn up. Foreign drug companies are considered for issue of industrial licences only for drugs in category (c) and even then, other things being equal the order of priority would be the public sector, Indian sector and last, the foreign sector.

(iv) Instructions have been issued to all State Drug Controllers that foreign companies should not be given any new loan licences. The turnover of the foreign companies based on existing loan licences will not be treated as Appendix-I activity but purely as trading activity.

(v) Foreign companies will not be eligible for any industrial licences for household remedies.

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(vi) The Small Scale Sector will be a prohibited area for foreign companies.

Essential Drugs

647. SHRI ARVIND GANESH KULKARNI:

SHRI SURESH SHAMRAO ' KALMADI:

Will the Minister of PETROLEUM, CHEMICALS AND FERTILIZERS be pleased to state:

(a) whether it is a fact that production of Anti-T.B., Anti-malaria, Anti-leprosy, Anti-dysentery and Anti-Phylarials drugs is far short of their installed capacities;

(b) if so, what are the reasons there, for, and

(c) what steps are being taken by Government to increase the production of these drugs in order to meet the demands in the country?

THE MINISTER OF RAILWAYS (SHRI P. C. SETHI): (a) Information on installed capacities for these drugs is not readily available. But the production of a majority of the monitored bulk drugs in these categories in the organised sector have gone up in 1981-82 compared to the previous year.

(b) The production of bulk drugs in this country would have been still higher but for reasons like non-availability of inputs like raw materials, power, water etc., lack of market demand, availability of cheaper imported drugs, out dated technologies and labour unrest.

(c) The following steps are being taken to increase the production of these drugs in order to meet the demands in the country: —

(i) Specific instances of nonavailability of inputs are looked into promptly and remedial action taken.

(ii) Additional capacities are being approved through issue of Letters of Intent and Industrial Licences whenever necessary for production of these drugs.

(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 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 view that in hospitalised 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