The annual capacities for these items have been fixed as indicated below: —

Items of manufacture	Annual Capacity
(i) Tetracycline Caps. (250 mg.) Nos. Tablets (250 mg.)	One Million
(ii) Chloramphenicol Capsules (250 mg.)	Do.
(iii) Chloramphenicol-Streptomycin Capsules (125 mg. plus 125 mg.)	Do.

(c) Pjowers to dispose 'COB' licence applications were vested with the Administrative Ministries concerned. Hence, approval of the Licensing Committee was not necessary.

Illegal manufacture of drugs by foreign companies

566. SHRIMATI MAIMOONA SULTAN: Will the Minister of PETROLEUM, CHEMICALS AND FERTILIZERS be pleased to state:

(a) whether it is a fact that M/s. Hoechst, M/s. Sandoz, M/s. Searle, M/s. Pfizer etc. have started marketing a number of drugs, manufactured through small scale units, under their own names;

(b) if so, what action Government propose to take in this regard; and

(c) what is the effect of this activity on foreign exchange position and whether Government intend to ban such activities?

THE MINISTER OF PETROLEUM, CHEMICALS AND FERTILIZERS (SHRI H. N. BAHUGUNA): (a) and (b) Government is not aware whether M/s. Hoechst, M/s. Sandoz, M/s. Searle, M/s. Pfizer etc. have started marketing a number of drugs manufactured through Small Scale Units under their own (brand), names.

However, M/s. Searle are selling products being produced by M7s. Sarala (P) Ltd., and M/s. Hoechst are selling products of M/B. Inga Labs. Pvt. Ltd., through marketing arrangements entered into between these firms, which are SSI units.

For entering into marketing arrangements companies do not require approval under I (D&R) Act.

(c) For use of brand names of foreign Companies, where direct or indirect outgo of foreign exchange is involved, prior permission under F.E.R.A. is required to be obtained.

Issue of COB Licences to foreign drug firms

567. SHRIMATI JAMUNA DEVI: Will the Minister of PETROLEUM, CHEMICALS AND FERTILIZERS be pleased to state:

(a) the number of COB licences issued to foreign drug firms operating in India with more than 26 per cent foreign equity during the last three years and in how many of them consolidated capacities were given; and

(b) whether it is a fact that the Industries Development and Regulation Act provides for grant of intent letters for every new item; if so, under what authority and on whose recommendations consolidated capacities have been given in the COB licences?

THE MINISTER OF PETROLEUM, CHEMICALS AND FERTILIZERS (SHRI H. N. BAHUGUNA): (a) During the last 3 years three COB Licences were issued to Drug Firms, with more than 26 per cent foreign equity. None of these were granted with consolidated capacities.

(b) No, Sir.

Short supply of drugs by multinational companies

568. SHRIMATI JAMUNA DEVI: Will the Minister of PETROLEUM, CHEMICALS AND FERTILIZERS be pleased to state:

(a) the drugs with their brand names which are in short supply in the country;

(b) what is Government's policy in respect ot' giving canalised items to the small scale sector and the organised sector; and

(c) what was the excess production ot bulk drugs, used for captive consumption for formulations, detected during the last three years and what steps Government have taken or proposed to take to safeguard the laws of the land which are being flouted by multinational drug manufacturing companies?

THE MINISTER OF PETROLEUM, CHEMICALS AND FERTILIZERS (SHRI H. N. BAHUGUNA): (a) Occasional shortages of some medicines with brand names have been reported by Drug Control Organisation, from time to time, from different areas of the country. However, in most of the cases, equivalent products of reputed manufacturers are generally available.

(b) Government Policy for release of canalised bulk drug's listed in the Annexure during 1978-79 is indicated below: —

(i) Small Scale Units:—In the year 1978-79', in the case of 4 drugs viz. Streptomycin, Amidopyrine, Doxycycline and Gentamycin, the small scale units shall be entitled to releases on the following basis:

(1) Small Scale Units having a turnover not exceeding rupees one crore per annum—to the extent of best of past 2 years' consumption plus 30 per cent towards growth.

(2) Small Scale Units with a turnover of Ks. 1 crore or above: —to the extent of best of past 2 years consumption plus 15 per cent towards growth.

AU new units *i.e.* units having no past consumption of the raw materials in question to the following extent: —

	Kgs.
(i) Streptomycin Sulphate .	25
(ii) Amidopyrine . . .	150
(iii) Doxycycline . . .	25
(iv) Gentamycin . . .	1

As regards the remaining items of Appendix 9 bf Import Policy 1978-79, except Vitamin D3, the policy for release of canalised bulk drugs is as follows: —

Additional allocations of raw materials for the year 1978-79 to S.S.I. Units shall be made to such an extent that their combined additional allocation together for 1977-78 and 1978-79 does not exceed 200 per cent of the allocations of the 18 bulk drugs listed in the annexure made in 1976-77 subject to the minimum allocation as admissible to the new units.

In the case of Small Scale Units set up in 1977-78, the canalised raw materials will be allocated either on the basis of a new unit ior the extent of allocations of raw materials made to that unit in the year 1977-78 whichever is advantageous to the unit.

In the case of Sulphamethoxazole and Trimethoprim which were not canalised for import in the year 1976-77 and fbr which consequently no allocations would have been made by the canalising agencies, the value of the Actual Users import authorised licences or releases obtained from indigenous manufacturers, if any, by the unit during 1976-77 duly certified by a Chartered Accountant would be taken into account and added to the *pverall* value of releases of other canalised raw materials for the purpose of determining' their entitlement for the year 1978-79.

New units are required to produce a photos copy of the drug manufacturing licence obtained from the concerned State Drug Controller and a certificate from their bank or the State or Central Financial Institution which finances them to the effect that their production plans as filed with them warrant the quantity of materials asked for.

New units wiH be allowed releases initially for total value not exceeding Rs. 3 lakhs. However, in respect of new units in the small scale seetor set up by the graduates/diploma holders in professional subjects or by ex-servicemen/persons belonging to Scheduled Castes/Scheduled Tribes or set up in backward areas, the maximum limit will be Rs. 5 lakhs.

(ii) DGTD Units (Organised Sector):—These units are entitled to canalised raw materials for the first 6 months of the year 1978-79 to the extent of 50 per cent of the releases of individual items made to them by the canalising agencies during 1976-77. DGTD units are also free to claim release of canalised raw materials on the basis of 50 per cent of their entitlements as per licensed capacities of individual formulations if the same are specified on their relevant industrial approval. Policy jor release of canalised raw materials to DGTD units during the second half of 1978-79 is yet to be announced.

(c) No study has been undertaken to ascertain the extent of excess production of bulk drugs used for captive consumption for formulations by drug manufacturing companies during the last three years. However, as per the Statement laid on the Table of the House on 29th March 1978 containing Government decisions on the (Hathi) Committee on Drugs and Pharmaceuticals Industry, it is proposed to issue a fresh consolidate^ licence to each company replacing all earlier licences issued under various licensing authorisations like industrial licence, c.o.b. licence, permission letter, registration certificate etc. In the process of such consolidation work it is expected that authentic data relating to excess production bulk used for captive consumption for formulations by multinational drug manufacturing companies as well as Indian drug manufacturing companies will become known.

The steps proposed to be taken by Government to regulate the operations of various sectors of the drug industry have already outlined in the Statement laid on the Table of the House on 29th March 1978 referred to above.

Annexure

1. Amidopyrine.
2. Ampicillin brihydrate/Ankaydrous/sodium.
3. Choloramphenico] Powder ChloraiphenicoL Palmitate, Chloromphanicol Stearate and Chloramphenicol Sodium Stearate.
4. Chloroquin and its salts.
5. Erythromycin (Base), Erythromycin Estolate, Erythromycin Stearate and Erythromycin ethyl Succinate.
6. Gentamycin
7. indomethacin.
8. Nethyl Dopa.
9. Metrenidazole.
10. Piperazine Anhydrous and Hexahydrate and salts of Piperazine.
11. Ribodavine (Vit. B2)
12. Streptomycin Sulphate.
13. Sulphamethoxazole.
14. Tetracycline, its salts and derivatives.
15. Thiamine Mono-nitrate and hydrochloride (Vit. Bl).
16. Trimethoprim.
17. Doxycycline.
18. Vitamin D3.