

distributed at a price of Rs. 1471/kg., although IDPL, declared a price of Rs. 4925/kg. Similarly, Phthalyl Sulphathiazole, another bulk drug produced by DIPL, was distributed at a price of Rs. 129.40/kg although IDPL declared a price of Rs. 173/kg.

(c) A statement containing detail to the extent available, is attached. [See Appendix CVII, Annexure No. 85].

**Manufacture of Federal C by M/s. Warner Hindustan**

1450. SHRIMATI JAMUNA DEVI: Will the Minister of PETROLEUM, CHEMICALS AND FERTILIZERS be pleased to state:

(a) whether it is a fact that M/s. Warner Hindustan are manufacturing Federal C Tablets without any industrial licence;

(b) whether any release of prednisolone was recommended in their favour; if so, under what authority and at what level the decision to release Prednisolone was taken; and

(c) what are the details of the instructions issued by his Ministry to the CPC in regard to Prednisolone releases?

THE MINISTER OF PETROLEUM, CHEMICALS AND FERTILIZERS (SHRI H. N. BAHUGUNA): (a) M/s. Warner Hindustan Ltd. applied to the Government in 1975 for Price approval in respect of Federal C tablets. The company were already manufacturing Federal tablets and it was considered that the party could take up the manufacture of Federal C tablets on the authority of an industrial licence obtained by them on 14-12-1962 although the composition of Federal C was not identical with the composition of Federal. The price approval was, therefore, granted to the company on 15-11-76.

Ministry of Law have since advised that change in the composition of an

existing formulation would also involve manufacture of a 'New Article'. In this context, the question as to whether the company should be asked to obtain a specific approval under the I(D&R) Act, 1951 for the manufacture of Federal C tablets, is being re-examined.

(b) On 21-2-1977, Warner Hindustan sought an *ad hoc* release of Prednisolone from this Ministry. In Ministry's letter dated 12th April, 1977, their request for *ad hoc* release was rejected.

2. On 20th April 1977, the Company furnished data required by the Government and again asked for *ad hoc* release of 60 kgs. of Prednisolone.

3. On 21st and 22nd June 1977, the party was informed as follow: —

"It would not be possible to allow additional release of Prednisolone to you so as to enable you to produce tablets beyond 1976 production level attained for tablets. Government is, however, prepared to permit you to produce 1 crore numbers of Federal C tablets, provided they are produced within the 1976 production level of tablets attained by you. If this condition is acceptable to your company, you may confirm the position directly to CPC as well as to this Ministry. On receipt of such as confirmation, CPC will release 15 kgs. of Prednisolone which would be adequate to produce 1 crore number of Federal C tablets."

4. In their letters dated 21st June 1977 and 6th July 1977, the company pleaded that they would not be able to comply with the condition that one crore Federal C tablets should be produced within the Company's 1976 tablet production.

5. In the meanwhile, the Company wanted instructions to go to CPC to release what they were entitled to on the basis of past consumption. A parallel development was that Wyeth's Prednisolone plant was closed down for a period of about four months from

-May 1977 to August 1977 and in this context, a general decision was taken that parties who had received allocation from Wyeth during 1976-77, would be given 40 per cent of their 1976-77 consumption of Prednisolone. As this applied to Warner Hindustan also, the following instructions were issued to the CPC on 5th November, 1977:—

"The matter has been examined further in the light of representation made by the party and it has been decided that they may be released at this stage, a quantity of 1.5 kgs. of Prednisolone which would equivalent to 40 per cent of their past consumption of 3.75 kgs. for the year 1976-77. The quantity to be released now will no doubt be a part of the ceiling of 15 kgs. of Prednisolone to be released to the Company for the year 1977-78, subject to the condition indicated in this Ministry's letter dated 2nd June, 1977."

6. In Ministry's letter dated 17th November, 1977, it was clarified to the CPC that in respect of the release of 1.5 kgs. of Prednisolone to the Company they need not impose the condition that the party would produce Federal C tablets within their 1.76 tablet production level, as this quantity was being released to them on the basis of their past consumption.

7. The above decisions were taken at appropriate level in the Ministry.

(c) In April 1977, M/s. Wyeth Laboratories who are the only manufacturer of Prednisolone in the country, were informed that they might make supplies of this drug to the same formulators only during 1977/1977-78 as per supplies made by them during 1976-77. For such supplies, no authorisation from the CPC would be necessary but M/s. Wyeth Laboratories could furnish a statement showing the production and supplies made to each formulator to the CPC and the Ministry every month. It is in this context that CPC were advised to make additional supplies of prednisolone to units

served by the CPC during 1977/1977-78 by way of growth rate as per distribution policy for release of canalised bulk drugs. CPC were also authorised to make supplies to any other units who wanted to take up the manufacture of products based on Prednisolone within the framework of distribution policy. Subsequently, the manufacturing plant of M/s. Wyeth Laboratories was shut down from May 1977, to August 1977 on account of some contamination problem resulting in loss of production. Instructions were, therefore, issued to the CPC that units serviced by M/s. Wyeth Labs in 1976/ 1976-77 may be allowed releases to the extent of 40 per cent of the quantities released to them by M/s. Wyeth Labs during 1976/1976-77. M/s. Wyeth Labs were also to be allowed similar release from the CPC. As regards new units, CPC were advised to release a quantity of 5 kgs of Prednisolone or the quantity recommended by the State Drug Controllers whichever was less.

Prednisolone has been decanalised during 1978-79.

#### Tube railway for the Madras city

1451. SHRI E. R. KRISHNAN: Will the Minister of RAILWAYS be pleased to state:

(a) whether there is any proposal under Government's consideration for providing tube railway system for the Madras City; and

(b) if so, what are the details in this regard?

THE MINISTER OF STATE IN THE MINISTRY OF RAILWAYS (SHRI SHEO NARAIN): (a) No.

(b) Does not arise.

#### Price of imported oil

1452. SHRI E. R. KRISHNAN: Will the Minister of PETROLEUM, CHEMICALS AND FERTILIZERS be pleased to state:

(a) whether it is a fact that the price of oil imported from the Arab