(c) what is the CIF value of the bulk drugs and CIF value* of the intermediates used per kilo of production?

THE MINISTER OF CHEMICALS AND FERTILIZERS (SHRI VASANT SATHE): (a) and (b) Of the five intermediates mentioned in the answer referred to, two are imported for the manufacture of bulk drugs which are licensed to the manufacturers for production from intermediate stages. Two other intermediates were being produced by manufacturers for captive consumption for producing their authorised formulations under Explanation II of the I (D & R) Act. Regularisation application of one of them (Merck Sharp and Dhome) for Cyproheptadine based on imported intermediate has been rejected. The regularisation application of the other (Burroughs Wellcome) for Allopurinoi is for production from the basic stagei. The import of Triene by Glaxo for the production of Betamethasone was a small quantity amounting to less than 5.4 per cent of the total Betamethasone produced. This company has been licensed to produce 428 kgs. per anuum of Betamethasone from the basic stages. Glaxo have stated that the imports were undertaken on account of technological problem! in the manufacturing process.

(c) Tht information is being collected.

Illegal production of Drugs by Foreign Companies

701. SHRI K. V. R. S. BALA SUBBA RAO: Will the Minister of CHEMICALS AND FERTILIZERS b_e pleased to refer to the answer to Unstarred Question 945 given in the Rajya Sabha on the 19th July, 1982 and •tate:

(a) whether Government are taking action against M/s. Pfizer, Glaxo and Warner Hindustan when it has been established that they have pro-•Imced certain New Articles in contravention of the provision of I (D & R) Act, 1951;

(b) what is the main notification of Government which authorises such companies to continue such illegal production after obtaining imported raw materials and canalised raw materials for the manufacture of such items;

(c) how DGTD authorised imports of these items before the OGL policy came into force; and

(d) whether Government have authorised regularisation of unauthorised and illegal production as a part of decision on New Drug Policy; if not, why this subject is being opened up now to give specific benefits to foreign companies?

THE MINISTER OF CHEMICALS AND FERTILIZERS (SHRI VASANT SATHE): (a), (b) and (d) A decision on the production of such items by individual companies will be taken after a general policy decision is taken regarding such instances of production of items for which authorisation have not been established.

(c) This came to notice after 1978 when the OGL Policy had already come into force. Imports of raw materials is governed by the Import Policy in force from time to time.

Criteria for High Technology Bulk Drugs

703. SHRI KRISHNA MOHAN BHAMIDIPATI: Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:

(a) what are the specific criteria out of twelve criteria laid down by High Technology Committee for high technology bulk drugs involved in the production of Ethoheptazine Citrate produced by M/s. Wyeth Labs., Diazepam and Chlordiazepoxide produced by M/s. Roche;

(b) whether these drugs are being produced by Indian Sector including small scale in the country; if so, names of the units, and the stage of manufacture;

(c) whether it is a fact that Indian companies are producing from basic stages whereas foreign companies from intermediate stages, if so, the details thereof;

(d) what are the critical stages of reactions which require control and sophisticated handling;

(e) whether the Committee on High Technology was only guided by the criteria involved in the production of the drugs or any other factor was also taken into consideration; and

(f) if so, what are the specific factors and the criteria connected with the process for the production of each of those three drugs of these two companies?

THE MINISTER OF CHEMICALS AND FERTILIZERS (SHRI VASANT SATHE): (a), (d), (e) and (f) The criteria for determination of nature of technologies differ from drug to drug and company to company for the same product depending on the process etc. involved. The processes were examined individually by the High Level Committee which consisted of eminent experts. The decisions of the Government were based on their recommendations.

(b) In the Indian organised sector production of Diazepam is being reported by M/s. Anglo French, M/s. Ranbaxy Lab, and M/s. Fairdeal Corporation and that of Chlordiazepoxide by M/s. Anglo French and M/s. Ranbaxy Labs. Ethoheptazine Citrate is not reported to be produced by Indian DGTD units. No production of these drugs by small scale units is being reported.

(c) Production of Diazepam and Chlordiazepoxide (also produced by Indian companies) by M/s. Roche Products is from basic and indigenous intermediate stages respectively.

Criteria Identified by Committee on HSgh Technology for production of Bulk Drugs

704. SHRI KRISHNA MOHAN BHAMIDIPATI: Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:

(a) what are the specific criteria out of 12 criteria identified by the Committee on High Technology which are involved specifically in the production of Vitamin E and Vitamin K by M/s. E, Merck(. Progesterone by M/s. Organon, Ibuprophen by M/s. Boots and Dapsone by M/s. Burroughs Wellcome giving the names of the criteria against each of these drugs by these companies only;

(b) whether the production of these drugs of these companies are from basic stages and whether these drugs are being produced by any other company in India; if so, from what stage; and

(c) whether it is a fact that the criteria involved in these drugs are also same and identical in the production of Propanolol, Hoi, Clofibrate, Tetmosol Cetrimide by M/s. Alkali Chemicals?

THE MINISTER OF CHEMICALS AND FERTILIZERS (SHRI VASANT SATHE): (a) to (c) The criteria for determination of nature of technologies differ from drug to drug and company to company for the same product depending on the process etc. involved. They were examined individually by a High Level Committee which consisted of eminent experts. The decisions of the Govt, were based on their recommendations. The manufacture of Vit. E and K (M/s. E. Merck), .Progestrone (M/s. Organon), Ibuprofen (M/s. Boots), Dassone (M/s. Burroughs Wellcome) and Tetmosol (M/s. ACCI) from basic stages by respective units was adjudged by the High Level Committee as involving high technology whereas the manufacture of Propranolol, Clofibrate and Cetrimide from basic stages by ACCI was adjudged as not involving high technology.