LOK SABHA

Thursday, March, 1994 Phalguna 12,1915 (Saka)

The Lok Sabha Met at Eleven of the Clock

[MR. DEPUTY SPEAKER *in the Chair*]

ORAL ANSWERS TO QUESTIONS

[*Translation*]

Spurious Drugs

*121. SHRI KHELAN RAM JANGDE
SHRI MOHAMMAD ALI ASHRAF FATMI:

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether the Union Government have received complaints from State level Food and Drug Administrations regarding pharmaceutical companies manufacturing sub-standard/spurious drugs:

(b) if so, the number of complaints receivved during each of the last three years, state-wise;

(c) whether the Union Government have issued instructions to State Governments and the purchasing agencies to black-list such pharmaceutical companies; and

(d) if not, the reasons therefor?

[*English*]

THE DEPUTY MINISTER IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI PABAN SINGH GHATOWAR : (a) No, Sir.

(b) to (d). Do not arise. Under the Drugs & Cosmetics Act and Rules, the State Drug Control Organisations are directly responsible for exercising control over the manufacture and sale of drugs including enforcement of standards set out in the Act.

Government has also instructed the State Licensing, authorities to step up vigil and launch punitive action against manufacturers and retailers of sub-standard/spurious drugs.

[*Translation*]

SHRI KHELAN RAM JANGDE : Sir, I do not agree with the reply given by the hon. Minister. Many pharmaceutical companies in the country, and especially in Madhya Pradesh, are not registered and they are not mentioned in the Government records also. I would like to know whether the hon. Minister will institute an enquiry against the companies manufacturing and marketing sub-standard/spurious

drugs?

[*English*]

SHRI PABAN SINGH GHATOWAR : I have already stated in my answer that under the Drugs and Cosmetics Act and the rules thereunder, the States are the Licensing agencies and they have to check within their States and take necessary action as stipulated in the Act.

[*Translation*]

SHRI MOHAMMAD ALI ASHRAF FATMI : Mr. Deputy Speaker, Sir, I want to know from the Government whether it is a fact that some of the patent drugs banned in European countries and in the Sub-Continent are being manufactured and prescribed in India? Secondly, many Homoeopathic, Unani and Ayurvedic medicines are being manufactured in India without conducting any research and they are being used by people in India. Therefore, I would like to know whether there is any agency to study the efficacy of these medicines and to do research in these fields of medicine to monitor the quality of these medicines and their proper administration?

[*English*]

SHRI PABAN SINGH GHATOWAR : About the Ayurvedic drugs, these drugs are manufactured on the basis of our old books that are prescribed in the texts, old texts of our country.

And these ayurvedic drugs are manufactured on the basis of that. There is no such system to check the quality of the ayurvedic drugs.

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI B. SHANKARANAND) : The hon. Member has raised a very important question. It is a fact that there has not been any testing laboratories for the ayurvedic drugs and we do not know whether these ayurvedic drugs which have been produced and manufactured by various manufacturing agencies really subscribe to the ayurvedic standards. Even the manufacturing agencies, the sales agencies of these drugs are not licensed as they are licensed in the case of allopathic drugs. The Drugs and Cosmetics Act does prescribe certain standards for the manufacture and sale of these drugs. It qualifies and defines sub-standard drugs, spurious drugs and lays down rules and regulations for inspection where the drug inspectors have to inspect the premises of the manufacturing agency, the sales units and storage facilities and they can take action, if necessary. In the case of ayurvedic drugs, these things are lacking. I think the hon. Member is right that we should take some action in this matter.

[*Translation*]

SHRI MOHAMMAD ALI ASHRAF FATMI : Mr. Deputy Speaker, Sir, my question has not been fully replied to. I wanted to know whether the medicines not being manufactured by the patent companies are being manufactured and sold in India? I had also asked about Unani and Homoeopathic medicines and the hon. Minister should have replied to these queries. Though many medicines are on the banned list, yet these, being sold...(*Interruptions*).....Please tell about Unani and Homoeopathic medicines.

[*English*]

SHRI B. SHANKARANAND: The hon.Member has asked a question with regard to the banned drugs in certain countries of the world, but which are being pro-

duced and sold in this country As far as banning of the drugs is concerned, in our country, we are guided by the advice of the Drug Controllers. Those drugs which are useful, which are life saving drugs and which are most essential for the people of this country, only those drugs are allowed to be sold in the market and not the other drugs.

DR. KARTIKESWAR PATRA; Mr. Deputy Speaker, Sir, I am very grateful to you for allowing me to raise this question. The Minister has stated that they have not received any complaint from the State level food and drug control administration regarding the pharmaceutical companies manufacturing sub-standard and spurious drugs. I want to know categorically from the Minister, whether there are any complaints from the public and whether the Government have any information regarding the action taken by the State level authorities against those manufacturers and retailars of sub-standard and spurious drugs. I would like to know whether that information is vailable with the Government; if so, in which State, against which company and what action has been taken against them.

SHRI PABAN SINGH GHATOWAR; I have already stated that samples of the drugs are collected by the State Drug Controllers. For the years 1991-92 and 1992-93, I have the list of how many samples have been collected and how many sample shave been not upto the standard. I have this list with me. The State Drug Controllers are taking steps according to the rules prescribed in the Act. If the hon. Member wants to know about a specific incident in a specific State, if he informs me about that, then I can mention about that State.

MR. DEPUTY-SPEAKER: If you need any further clarifications, the hon. Minister is ready to suply you with that information.

[*Translation*]

SHRI VIJOY KUMAR YADAV : Mr. Deputy Speaker, Sir, under the new economic policy of the Government and the Dunkel Proposals, the prices of the medicines will increase appreciably and common man will find it hard to purchase the medicines. Under these circumstances spurious drugs will flood the market. In view of the above whether the Government propose to take steps to ensure availability of genuine drugs at reasonable rates to the people?

[*English*]

SHRI B. SHANKARANAND: The hon. Member has asked a question about the manufacturers of spurious drugs. I want to inform the House that there are about 28 thousand registered manufacturers of these drugs in this country out of whom only five thousand are in the large scale and medium scale. The rest are just small scale manufacturers. There are 15 thousand people who are small manufacturers. Because they are small, they have not been able to afford the maintenance of drug testing facilities in the laboratories and the necessary standard conditions in the premises for producing standard drugs. They are all recent manufacturers who are manufacturing medicines. They are selling the drugs in the market and people are buying those medicines.

The spurious drug manufacturers are not registered ones. They do it very clandestinely. They are not only doing it privately, but are doing it in a very secret and confidential manner. They want to avoid the police and the inspecting authorities. To control them, the public has to cooperate with the law enforcing machinery of the Government. The drug controllers both in the States and at the Centre do take care of it.

Translation]

SHRI VIJOY KUMAR YADAV : In view of the fact that spurious drugs are being manufactured on large scale, whether the Government propose to take any stringent measures to check it? such activities?

[*English*]

SHRI B. SHANKARANAND; There are laws to prevant this. We need the cooperation of the people with the police for this purpose.

SHRIMATI MALINI BHATTACHARYA; Just now the Minister has spoken of small scale drug companies coming up with substandard drugs. However, if one refers to the Lantin Commission report, and finds that the multinational: companies and the large drug companies are equally responsible or more responsible for the manufacture of such substandard drugs. In view of the fact that the Operational Research Group has recently come out with certain data which show that out of 77 top selling drugs, about 23 are either hazardous or irrational or both, I would like to know from the hon. Minister what the Central Government intends to do to implement the World Health Organisation guidelines regarding ethical criteria for medicinal drug promotion which was adopted by the world health assembly in 1988. India being a signatory to this, the Government has to ensure that in the public health distribution system these criteria, the code of the world health assembly are maintained. What is the Central Government doing about that?

SHRI B. SHANKARANAND: The hon. Member has mixed up various questions in one lot. The hon. Member is rightly concerned with these things. Regarding WHO ethical standards to which we are a signatory, of course we do adhere to the principles that we have signed for. We should know that we have a law in this country to control, to regulate, to prevent the manufacturing and selling of spurious and substandard drugs.

A very well laid law and the detailed provisions present all these things. Hon. Lady Member has asked as to whether we are taking into consideration the ethical principles laid down by the WHO while controlling and regulating the manufacturing process of various important drugs in this country. I can only say that we have taken all this into consideration. We allow manufacture, sale under the law, of those drugs which conform to the standards.

[*Translation*]

SHRI DAU DAYAL JOSHI: Mr. Deputy Speaker, Sir, the hon. Minister has stated that as Ayurvedic medicines are manufactured on the basis of prescribed formulations given in the books, there is therefore, no check on their preparations. 'Sitopladi Churna' is prepared on the basis of one such formula. However, four ingredients out of the five required for this formulation are spurious. The ingredients like Tugakshiri, Pipli, Vanshraj, Vajay or Peepal, Vanshlochan, Dalchini, Cardamom etc. are not available in their original form. Only 'mishri' in its original from is available. 'Vanshlochan' is not available anywhere in the world. That is why the Indian Ayurvedic companies are using calcium as an alternative ingredient for manufacturing 'sitopladi churna'. Ayurvedic medicines are popular all over the world. In 1992, we exported Ayurvedic medicines worth Rs.3 crore, in 1993, the export value of these medicines was Rs. 7 crore and till December, the exports had touched the mark of Rs. 74 crore. But the Government has imposed a 10 per cent tax on these medicines...(*Interruptions*)...Hingashtik churna' is very popular. Spurious 'heing' is available at the rate of Rs.3 per tola whereas the price of genuine'heing' is Rs.70 per

tola. In view of the prevailing circumstances whether the Government have taken measures to ensure a check on the quality of ingredients used in ayurvedic drugs?

[*English*]

SHRI B. SHANKARANAND: Sir, the hon. Member is a very well informed member about the ayurvedic system of medicins. (*interruptions*). He is a learned ayurvedic physician. I can only share his concern for what is happening to these medicines in this country. I very will appreciate the suggestion made by the hon. Member in this regard to prevent, regulate and control the manufacturing of spurious ayurvedic drugs in this country. It does need consideration and the suggestion which he has made deserves consideration.(*interruptions*)

MR. DEPUTY-SPEAKER; Please exuse me, (*Interruptions*)

MR. DEPUTY-SPEAKER : This question has consumed nearly 28 minutes; and there are other questions (*interruptions*)

MR. DEPUTY-SPEAKER ; In fact, for many of the very important Supplementaries which are put, the hon. Minister was able to reply to them. (interruptions)

MR. DEPUTY-SPEAKER; This question has taken nearly 28 minutes; and now, we shall go to Question No. 122.

[*English*]

Gas from Bombay High

* 122. DR. VASANT NIWRUTTI PAWAR :
SHRI GOVINDRAO NIKAM:

Will the Minister of PETROLEUM AND NATURAL GAS be pleased to state:

(a) the State Governments which have sought supply of gas from Bombay High till January 1, 1994;

(b) the details of the quantum of gas sought by each of these State Governments;

(c) the decision taken by the Government in this regard; and

(d) the details of power projects considered for supply of additional available gas from Bombay High other than in Maharashtra?

THE MINISTER OF STATE OF THE MINISTRY OF PETROLEUM AND NATURAL GAS (CAPT. SATISH KUMAR SHARMA) (a) and (b) Requests for allocations for power and other projects have been received from Maharashtra, Gujarat, M.P., Rajasthan and U.P.

(c) and (d). Allocations to the extent of 55.60 MMSCMD have alrady been made from the Western Off shore fields including 16.55 MMSCMD to Maharashtra.

Apart from the power plants of MSEB and TEC in Maharashtra, NTPC's plants at Anta in Rajasthan, Auraiya and Dadri in U.P., Kawas in Gujarat, Faridabad in Haryana and DESU's plants in Delhi and Bawana have been allocated gas.

DR. VASANT NIWRUTTI PAWAR; Sir, the hon. Minister has not replied to my question about the quantum of gas sought by State Governments. As per the zero flaring plan of Government of India for reduction of flaring of gas at Bombay High, the entire additioinal gas available is to be taken for fertiliser and power projects and other units in the North by the HBJ pipline. This plan is capital-intensive and time-consum-