*86. [The questioner (Shrimati Sushma Swaraj) was absent. For answer *vide* page 20 infra]

Substandard drugs

*87. SHRI A. ELAVARASAN: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether it is a fact that many drugs produced by the well known pharma companies are substandard;

(b) if so, whether Government has conducted any survey to find out the quality of medicines produced by well known, leading pharma companies;

(c) if so, the details thereof; and

(d) the action taken by Government against those companies whose products were found substandard?

THE MINISTER OF HEALTH AND FAMILY WELFARE (DR. ANBUMANI RAMDOSS): (a) to (d) A Statement is laid on the Table of the House.

Statement

(a) There are no reports that many drugs produced by the well known pharma companies have been reported to be substandard. The drug manufacturers are required to test each batch of the finished product in their own laboratory or laboratories approved by the State Licensing Authority before release of drugs for sale. The drug products are manufactured under licenses granted by the State Licensing Authorities after ensuring that they comply with the conditions of the license. Manufacturing premises are inspected by State Drugs Inspectors to ensure that they conform to Good Manufacturing Practices. However, because of long distance transportation, wide variation of temperature and improper storage, deterioration may occur in certain cases. The check on the quality of the drugs marketed in the country is earned out through random sampling by the Drugs Inspectors appointed by various State Governments.

(b) and (c) No survey has been conducted to find out the quality of drugs produced by any specified category of manufacturers by the Government of India. However, it has been decided to conduct a study to know the extent of spurious drugs in the country, for which samples have already been collected from across the country.

(d) The State Licensing Authorities take action against the manufacturers whose products are found not of standard quality depending upon the nature of defects under the provision of the Drugs and Cosmetics Act and Rules made thereunder.

SHRI A. ELAVARASAN: Mr. Chairman, Sir, the answer given by the hon. Minister is not satisfactory as it seems that the hon. Minister is intending to say that it is a State subject. In view of the above answer given by the hon. Minister, I would like to know from the Minister whether the Government is procuring medicines for Central Government hospitals and CGHS dispensaries and the State Governments.

DR. ANBUMANI RAMDOSS: Sir, I don't know how relevant this question is to the main question. But, Sir, today, we have a specific structure. The policy decisions are taken by they Central

Government and enforcement is done by the State Governments. At the national level, we have the Central Drug Controller General of India, and at the State level, we have the State Drug Controller and other licensing authorities. They give licences for manufacturing. For any new molecule that the Central Government approves, the State Government provides licences to the units. The entire regulatory mechanism is of the State Government. The State Governments are responsible for enforcing quality in any of the drugs supplied in their States.

I now come to the question raised by the hon. Member. The hon. Member raised the issue about procurement by the Central Government. It is through national tenders and international tenders. They are need-based tenders. Anybody could apply it at any point, of time. If they qualify, they will be eligible for getting themselves registered with the Central Government.

SHRI A. ELAVARASAN: Sir, there is huge supply of sub-standard and spurious drugs available in the market in the name of leading pharma companies. I would like to know whether the Government has constituted any strict monitoring committee to prevent production and sale of fake drugs in the market and to ensure that such sub-standard drugs are not mingled with the usual drugs procured for the Central Government hospitals and CGHS dispensaries.

DR. ANBUMANI RAMDOSS: Sir, if the hon. Member has any information about any specific product or any company and he shares that with us, we will, definitely, inspect it. Nevertheless, I would like to say that in the last couple of years we have taken a number of steps to streamline the process for checking spurious drugs or adulterated drugs or sub-standard drugs or the drugs which are not of standard quality. Sir, these are the four categories in India. I would like to say that we, in fact, amended the Drugs and Cosmetics Act last year, in the last Session, whereby we recommended stricter penalties, legal and penal implications if anybody is found selling spurious drugs or adulterated drugs. I would like to say, Sir, that the amendment was passed by both the Houses. It is now there to be notified. The penalty for anybody selling a spurious drug by which some person dies or grievously injured is minimum 10 years imprisonment and maximum life imprisonment. So, it is there in the Act. Plus the individual or the company has to pay a fine of Rs.10 lakh or three times the value of goods confiscated, whichever is more and this money will be given to the relatives of the victims. These are some of the implications that we are streamlining. Sir, we have also gone for strengthening the capacity. The State Government drug labs and the Central Government drug labs are being strengthened. In fact, some of them have been strengthened, modernised and capacity built. Then, we have put up more Drug Inspectors also. The UPSC have been selecting Drug Inspectors at the national level, the State level, the State Governments are supposed to appoint the Drug Inspectors. That is another point.

The third point is that we have, again, recommended one more amendment to the Drugs and Cosmetics Act whereby we will be having a Central Drug Authority. This was recommended by Dr. R. Mashelkar and others. We have gone through this. The Standing Committee has examined this issue. They have given the recommendations and now we are taking it to the Cabinet. We would,

again, put it back to Parliament. This is the structure which had been required for the last 30, 40 years and, ultimately, we are doing it. We have gone through a lot of discussion process. Now, Sir, the building is ready. We have inaugurated the building. The entire structure is there. And, the Drug Authority will have divisions of drugs, vaccines, ayurvedic products, medical devices, etc.

MR. CHAIRMAN: Thank you. Let us get on to the next supplementary.

SHRI S.S. AHLUWALIA: Sir, 'standard' means quality, quantity and price. I have with me a price list of Livo Proxacine. The cost of ten tablets is Rs.80/- and the cost of five tablets is Rs.800/-. Why is this so? One doctor told me to take five tables for Rs.800/- because that will be useful. All tables are of 500 mg. How is it different? Is it sub-standard? Have you checked up this? Why are they doing so? Why is one tablet of Rs.800 equal to three tablets?

DR. ANBUMANI RAMDOSS: Sir, 'pricing' does not come under my Ministry. My colleague, Mr. Paswan's Ministry handles the pricing issue. Nevertheless if you can give me some more information about that, I would, definitely, give it to my colleague, Mr. Paswan.

श्री अवतार सिंह करीमपुरी: सर, मंत्री जी ने अपने जवाब में कहा है कि no survey has been conducted to find out the quality of drugs, जबकि यह बहुत ही गम्भीर मामला है। मैं आपके माध्यम से मंत्री जी से यह जानना चाहता हूं कि अगर आपने drugs की quality को control करने के लिए पहले कोई सर्वे नहीं कराया है, तो क्या आइन्दा सर्वे कराएंगे? सर, मेरे प्रश्न का दूसरा भाग यह है कि मार्केट में जो new product launch किया जाता है, उसका क्या procedure है?

DR. ANBUMANI RAMDOSS: Sir, there have been some issues about India being a spurious drug market which is completely unconfirmed. India has the highest US FDA approved Pharmaceuticals outside the United States. So, that quality standard we are having. Surveys have been done and now we are in the midst of huge surveys being done by the Department itself. The earlier survey was done by the SEAR-Pharm Forum in association with the SEARO region of the WHO. They have been involved in that, and they have said that the extent of counterfeit suspects was to the tune of about 3.1 per cent, the suspected. But the actual, they say, is even low. It is even lower than that.

Coming to the new drugs, Sir, with regard to some of the new drugs we have, there are these Pharmaco Vigilance Committees all over the country, and any suspected adverse drug reactions or post-marketing surveillance reaction, etc., will be monitored by these Pharmaco Vigilance Committees.

MR. CHAIRMAN: Question Hour is over.

WRITTEN ANSWERS TO STARRED QUESTIONS

Export of sugar

*81. DR. T. SUBBARAMI REDDY: Will the Minister of CONSUMER AFFAIRS, FOOD AND PUBLIC DISTRIBUTION be pleased to state: