

RAJYA SABHA

Monday, the 15th March, 1982/
24th Phalguna 1903 (Saka)

The House met at eleven of the clock. Mr. Chairman in the Chair.

ORAL ANSWERS TO QUESTIONS

Formulations of foreign drug Companies

*281. DR. JOSEPH LEON D'SOUZA: Will the Minister of PETROLEUM, CHEMICALS AND FERTILIZERS be pleased to state—

(a) what are the formulations of M/s. Glaxo, Pfizer, Sandoz and Burroughs Wellcome which have been reported to be in short supply during the last two years;

(b) whether these companies have not produced these products in adequate quantities, particu-

larly as compared to other products like Septran Tablets, Griseofluvin Tablets, Oxytetracycline base formulations which they are producing far in excess of licensed capacity and also in violation of the conditions of Industrial Licences; and

(c) whether it is a fact that these companies are producing more products of high profits and less of essential products?

THE MINISTER OF PETROLEUM, CHEMICALS AND FERTILIZERS (SHRI P. SHIV SHANKAR): (a) to (c) A Statement is laid on the Table of the House.

Statement

(a) During the years 1980-81 and 1981-82 the following formulations produced by M/s. Glaxo, Pfizer, Sandoz and Burroughs Wellcome were reported to be in short supply from time to time in different parts of the country

M/s. Glaxo

1. Grisovin Tablets

2. Eitroxin Tablets

3. Scoline Injection

M/s. Pfizer

1. Isonex Tablets

2. PAS Granules

3. Terramycin Capsules

M/s. Sandoz

1. Brinerdin Tablets

2. Syntocinon Injection

3. Methergin Injection

M/s. Burroughs Wellcome

1. Tubarin Injection

2. Thyroid Tablets

3. Myleran Tablets

4. Lukeran Tablets

(b) With reference to the reported shortages of these products from time to time, the manufacturers reported problems relating to production such as (i) limited availability of imported raw materials (in the case of Erinerdin Tablets, Tubarin Injection and Thyroid Tablets) (ii) industrial unrest (all items of Pfizer), (iii) power cuts (Myleran and Lukeran Tablets), and (iv) increase in demand (Eltroin, Syntocinon and Methergin). The production in 1980-81 of Grisevin Tablets and Scoline Injection was in excess of licensed capacity. Production of many other items of these companies including Septran of Burroughs Wellcome has also been in excess of licensed capacities. All the four companies have applied for recognition of » installed capacities where they are in excess of licensed capacities.

(c) The number of formulations not covered by price control produced by these four companies is very much less than the number of price controlled formulations produced by them.

DR. JOSEPH LEON D'SOUZA:
Mr. Chairman, I would like to make a few observations
(Interruptions)

SHRI JAGDISH PRASAD MATHUR: Sir, some questions are being repeated and accepted in this Session for the third time. The same questions have been asked repeatedly. I do not know what has happened. ****Other questions are not being taken up. Why this question is being repeated? (Interruptions) There is some mistake...

MR. CHAIRMAN: Third question ...

*Expunged as ordered by the Chair.

SHRI JAGDISH PRASAD MATHUR: The third question; it is the third time in this very Session.

MR. CHAIRMAN: Let us not...

SHRI JAGDISH PRASAD MATHUR: There should be some mistake somewhere. (Interruptions) Other questions have been rejected for nothing. I am sorry to say this; some of the questions are being rejected summarily. Some people are interested in...

MR. CHAIRMAN: Do not lose your...

AN HON. MEMBER: The matter should be enquired into.

SHRI JAGDISH PRASAD MATHUR: It is repeatedly...

MR. CHAIRMAN: Mr. Mathur the same thing can be said gently. Do not lose shirt on it.

श्री तिव चन्द्र झा : जब हम पूछते हैं
ता... (बयवधान) कह दिया जाता है...
(बयवधान) इसका जवाब दे दिया गया है।
(बयवधान)

MR. CHAIRMAN: I have understood it.

SHRI JAGDISH PRASAD MATHUR: Even the questions which were tabled days ago have been rejected. But the same question is coming up over and over again.

MR. CHAIRMAN: When the question has been asked....

SHRI JAGDISH PRASAD MATHUR: What is the interest? (Interruptions)

MR. CHAIRMAN: Mr. D'Souza, you have put the question and the Minister has said that a statement has been laid on the Table of the House. Any supplementary?

UK. JOSEPH LEON D'SOUZA: At the outset, my hon. friend is correct. But he is unaware of the fact that to a question there are several facets and all the facets cannot be brought out at one time. Now, with reference to that the Government of India was pleased to grant certain licences for the manufacture of drugs and formulations specifying and definitely, • quantifying the licensed capacity for them. I am on this valid point on which my question will depend. Sir, it is my observation that these drugs are manufactured ... (*Interruptions*)

MR. CHAIRMAN: Order, order.

DR. JOSEPH LEON D'SOUZA: ' Sir, the drugs manufactured or formulated, can very easily be categorised into three categories. ' Some are manufactured far above in excess of the quantity quantified for manufacture. ...

MR. CHAIRMAN: Very well.

DR. JOSEPH LEON D'SOUZA: . . . but some much less, alarmingly less, and others not at all, not even the process for their manufacture is initiated.

MR. CHAIRMAN: What is the fourth category—manufactured at -all or not?

DR. JOSEPH LEON D'SOUZA: It is also observed that those drugs that are manufactured alarmingly in excess are those that produce lucrative profit. The other—I am coming to my point—are the vaccines, for instance. I am a medical man. Vaccines comprise triple antigen, whooping cough. These two are very essential in the medicare of children, the Bharat of tomorrow. Sir, take, for instance, antitetanus, the life-saving drug. Once you get tetanus, you are booked; there is no other way. You will notice that the licensed capacity is 2,400

litres. It is amazing to note that only 312 litres were manufactured. Sir, the Prime Minister and her Government are wedded to the cause of catering to the masses and the best form in which we can do it is to see that it is implemented. Another instance is that of septron. For the production of septron 1.8 ton of Trimethoprim is the sanctioned quantity. Sir, it is alarming to note that almost 20 tonnes are used. May I tell the hon. Minister that there is a ceiling fixed for the production! of drugs—ceiling on production capacity...

MR. CHAIRMAN: Yes, he understands that.

DR. JOSEPH LEON D'SOUZA: Anything which is 25 per cent in excess is permissible in manufacture, the rest is a violation of the contract. Sir, will the hon. Minister be kind enough to throw some light on this subject and say as to how these companies are producing 25 per cent above their licensed capacity? And may I take this opportunity. Sir—I personally met the hon. Minister after the last question hour to apologise for something which I had inadvertently said last time. He is an excellent gentleman, but I feel that he is not advised correctly by his Department. (*Interruptions*)

SHRI P. SHIV SHANKAR: Sir, I thank the Eon. Member. He need not apologise. I am grateful to him. He was so kind to me. But my only lament is that he has not been a little kind to my officers. Sir, I must say that—not that I am trying to unduly support my officers...

MR. CHAIRMAN: I think you better get on to the question.

SHRI P. SHIV SHANKAR: I am coming to the question. But let no impression go that we are

guided wrong by our officers. We are also to protect the administration to the extent it deserves, to the extent it is required. On the question of the licences that are granted...

MR. CHAIRMAN: Over-production, under-production and no production. It could be put in three words. He has taken five minutes.

SHRI P. SHIV SHANKAR: Sir, it is no doubt true that in a large number of cases the indigenous companies as also the foreign companies have more installed capacity than the licensed capacity and many companies, indigenous and foreign both are manufacturing more drugs than the licensed capacities because of their...

MR. CHAIRMAN: ..product being remunerative.

SHRI P. SHIV SHANKAR: Not exactly remunerative.

MR. CHAIRMAN: That is what the allegation was.

SHRI P. SHIV SHANKAR: Let me make my submission.

MR. CHAIRMAN: Your submission you will have it.

SHRI P. SHIV SHANKAR: Because the installed capacity is more. There was a press note issued on 29th August 1980 by the Industry Department. This is a general press note with reference to all the industries. And the sum and substance of this press note was to recognise installed capacities of manufacturers, both Indian and foreign, so that there will be no difficulty with reference to their production so that it may be regularised even if it is more than the licensed capacity. With reference to the drugs specifically my Department issued, I having regard to the drug policy,

on the 17th October, 1981, a separate press note which is in conformity with the press note that was issued by the Industries Department and placing certain hedges according to the drug policy. I would not like to go into those conditions which have been imposed by us but in the ultimate analysis, the approach that we had to take was in accordance with the general industrial policy. This is a case of regularisation of capacities of indigenous and foreign companies, both.

DR. JOSEPH LEON D'SOUZA: Sir, I come to my second supplementary. As you very clearly said, some produce more,, some produce less and some do not produce at all. That is the background. In view of the background that some companies have not been producing some drugs that they had to produce for a period of over eight to ten years, it is alarming to notice that despite the fact that apprehensions have been voiced in this House, here is an attempt to revive the lapsed letters of Intent for the manufacture of Salbutamol against all norms laid down by the Department for its procedure. The letter of intent was issued more than eight' to ten years ago. It lapsed. The Legal Department opined that it had lapsed. \ Now there are certain definite procedures for a letter of intent. When a letter of intent is given, it is valid for one year. It can further be extended by six months and another six months "under valid reasons. After two years, the licence lapses if it has been extended. Now my question is specific: why this unearthly or undue' interest to revive the letter of intent which has lapsed? Apprehensions have been expressed in this House so often.

SHRI P. SHIV SHANKAR: Sir, may I submit that this is covered by Question No. 233? My friend

may put that question at that stage.

DR. RAFIQ ZAKARIA: How can be?

SHRI P. SHIV SHANKAR: This is with reference to a different issue. He is asking with reference to Salbutamol.

THE MINISTER OF INFORMATION AND BROADCASTING (SHRI VASANT SATHE): Why not club them together?

DR. RAFIQ ZAKARIA: Club them together.

DR. JOSEPH LEON D'SOUZA: Let me explain.

MR. CHAIRMAN: Clubbing is not possible now, Dr. Zakaria. *(Interruptions)*

SHRI P. SHIV SHANKAR: Sir, may I request you to look up Question No. 283 for a while?

MR. CHAIRMAN: Yes, yes, I have seen it. There is a request that a half-an-hour discussion should be allowed on it.

SHRI P. SHIV SHANKAR: That is ultimately your discretion.

MR. CHAIRMAN: I am saying that we have not reached it.

SHRI P. SHIV SHANKAR: That is what I am saying...

SHRI VASANT SATHE: We are not likely to reach it at this rate.

SHRI P. SHIV SHANKAR: Would you like me to answer this question which has been raised? *(Interruptions)* It is true that in 1971 a letter of intent was issued to Glaxo for the purpose of manufacturing the bulk drug Salbutamol. Some condition was imposed and the condition was that 50 per cent of this bulk drug should be supplied by this company to the non-associated formulators. They

had been representing against that condition. Then, it so happened that in 1974 the Hathi Committee was appointed which gave its report in 1975. In 1976 a decision was taken that these matters should await the decision on the Hathi Committee's report. So, after the decision was taken in 1978, again we repeated the same condition, we said it is not possible for us to forego that condition. As late as in 1980 the Company came forth with the reply saying that they accept the condition. Then the question was whether the letter of intent still survived or whether it lapsed. That question is still under consideration...

DR. RAFIQ ZAKARIA: Since 1978?

SHRI P. SHIV SHANKAR: One has to concede, in a democracy slow-motion process has got to be accepted.

DR. JOSEPH LEON D'SOUZA: One clarification. The question I asked was when the letter of intent lapsed because of non-production by the company, why it is that we are still wanting to give this company which has not fulfilled its own duty. That is my supplementary.

SHRI P. SHIV SHANKAR: Each case will have to be decided on its facts. Since in this case a particular company had been raising objections and they were in correspondence, the matter was delayed. In fact, this matter will be disposed of ...

MR. CHAIRMAN: Why don't you say in plain words that somebody else wants the licence?

SHRI P. SHIV SHANKAR: Somebody else wanted the licence and that has been already granted.

MR. CHAIRMAN: But it lapsed. . . . j

SHRI P. SHIV SHANKAR: That is a different issue altogether. Somebody asked for the licence expansion, and that was granted as late as in 1981 even. Therefore, it is not a question of anybody having been denied because of the fact that a particular company had obtained the letter of intent and the matter is still in the disposal stage. Not so. Those who came in between have already been granted from time to time. I am prepared to give details about it ...

MR. CHAIRMAN: When the request comes, it would be much better. I will finish the question first,

SHRI MURLIDHAR CHANDRAKANT BHANDARE: This problem is of national concern. The multinationals, I think, instead of bringing in really advanced technology and giving it to our country, what we find here is most of these multinationals: are grossly guilty of breach of their primary duties of developing the basic drug bringing in higher technology, advanced technology to their manufacturing formulations which really involve very low technology and very low cost but maximum profit. They are subjected to FERA under which they must bring down the equity to 40 per cent. But nothing has been done. In fact, most of us, Members of this House, as well as in the Consultative Committee, have been feeling considerably agitated and exercised over the protection which he...

MR. CHAIRMAN: We have been repeating it almost every other day.

SHRI MURLIDHAR CHANDRAKANT BHANDARE: We have discussed it threadbare, decisions have been taken, and yet not implemented. My Lord
— (Interruption)

MR. CHAIRMAN: Force of a bad habit.

SHRI MURLIDHAR CHANDRAKANT BHANDARE: The habit is good elsewhere. May I ask the Minister whether he would insist on these multinationals fulfilling their basic obligations to our country and till they fulfil those obligations, the Government does not encourage them in any manner by granting any further licence?

SHRI P. SHIV SHANKAR: Not granting the further licences is a big question. It depends on the technology. If it is available here. I assure the House that...

MR. CHAIRMAN: What is the big question? It depends on the facts of the case.

SHRI P. SHIV SHANKAR: I may not be accused of evading the answer. The point is if it is a case where the technology is not available in this country and we require the drug, we will have to necessarily grant the licence...

SHRI PILOO MODY: Why do you commit yourself?

SHRI P. SHIV SHANKAR: That depends again—each case will have to be looked into on the question of technology. So, the facts might differ. It is difficult for me to give a clear commitment; that we will not give the licence to these companies at all is a matter which I cannot concede.

DR. JOSEPH LEON D'SOUZA: Sir, one clarification...

MR. CHAIRMAN: I cannot renew your licence any more.

DR. JOSEPH LEON D'SOUZA: Only one clarification...

MR. CHAIRMAN: Mr. D'Souza, I cannot allow you to interfere.

SHRI HARI SHANKAR BHABHRA: Mr. Chairman, I rise to inform you that this question is being repeated in this House from time to time by Members from one party. I can give you the details. Question No. 1759 on 7th September, 1981 ...

MR. CHAIRMAN: You can show me that later and I will see it.

SHRI JAGDISH PRASAD MATHUR:***

SHRI HARI SHANKAR BHABHRA: Sir, my point is that there are two opinions among the ruling party members. One section is supporting the Glaxo Company and the other is opposing it. And the Government is always evading the reply and side-tracking the issue ... (*Interruptions*).

DR. RAFIQ ZAKARIA: Sir, this is a reflection on our Members. They have a right to ask any supplementary. ... (*Interruptions*).

MR. CHAIRMAN: Order, order.

DR. RAFIQ ZAKARIA: You should expunge his remark.

SHRI PILOO MODY: I am not quite clear whether Dr. Zakaria is supporting M/s. Glaxo Company or opposing them.

DR. RAFIQ ZAKARIA: I am saying that any Member has the right to ask questions in this House and * * * one member of the party puts a particular question on the subject whereas another member of the same party puts a different question on the same subject.

SHRI JAGDISH PRASAD MATHUR:* * *

SHRI HARI SHANKAR BHABHRA: Sir, I can give even the names.

*Expunged as ordered by the Chair.

MR. CHAIRMAN: What is your question?

SHRI HARI SHANKAR BHABHRA: My question is this. It has been made very clear to the Government that there are certain drugs, for example, Salbutamol, which can be manufactured in India by our own companies. The Government also has made this clear. In spite of that the Glaxo Company is given licence over and over again. . .

MR. CHAIRMAN: This is question No. 283.

SHRI HARI SHANKAR BHABHRA: I was giving an example. Similarly, licences have been issued to the Glaxo Company. Still, they are not manufacturing; the drugs according to the terms and conditions of the licence. This has been raised in the Parliament, both in this House and in the other House. And the multi-national companies are being supported by somebody, somewhere in the Government...

MR. CHAIRMAN: Are you charging the Government or are you asking the question?

SHRI HARI SHANKAR BHABHRA: I am charging the Government for evading replies. The Government must say that they will either ban the import of those items which can be manufactured here by our own companies, or they will allow the multi-nationals to import them and throw this extra burden on our people ... (*Interruptions*).

DR. RAFIQ ZAKARIA: What has their Government done during their rule of 24 years.. (*Interruptions*).

SHRI HARI SHANKAR BHABHRA: The hon. Member who is interrupting me*** why should he

interrupt me? Now, I am asking any question...

SHRI N. K. P. SALVE: On a point of order. May I invite your attention to rule 47(2) (iv)? This rule says:

"it shall not contain arguments, inferences, ironical expressions, imputations, epithets or defamatory statements"

SHRI PILOO MODY: Under what head he is putting it?

DR. RAFIQ ZAKARIA: He is imputing.

SHRI HARI SHANKAR BHABHRA:***.

MR. CHAIRMAN: I have understood it. But if this rule is rigorously enforced in the House, three-fourths of the questions will go out.

SHRI PILOO MODY: He is imputing himself.

SHRI N. K. P. SALVE: Sir, there are certain types of imputations. So far as we are concerned, Sir, all these multinationals should be lumped together and sent away altogether. That is our approach and that is our attitude. (Interruptions)

MR. CHAIRMAN: That is all sight.

"SHRI N. K. P. SALVE: And, therefore, to say that there is*** -or the other is an extremely unfair approach to the whole problem. . .

SHRI PILOO MODY: Not at all. (Interruptions).

SHRI N. K. P. SALVE: ... and we will not be able to act fearlessly. (Interruptions) Sir, we will not be able to act fearlessly if this sort of an intimidation is there. Ultimately, one side or the other

***Expunged as ordered by the Chair.

has to be taken. If you take one side or the other and for that if motives are attributed or imputations are there, it would only impede our acting fearlessly. (Interruptions),

MR. CHAIRMAN: That is all right. (Interruptions)

SHRI ARVIND GANESH KULKARNI: Sir, ...

MR. CHAIRMAN: What are you trying to do? (Interruptions)

SHRI ARVIND GANESH KULKARNI: Sir, I am quoting rule 47 which *** Mr. Salve has quoted. (Interruptions) Sir, with due regard to my friends sitting here, I am sorry to point out one thing. Never during the last fifteen years, during which I have been a Member of this House, have Members imputed motives against the Secretary-General any time nor have we ever tried to impute any motives either to the treasury benches or to the Opposition benches which is a sad reflection on the Members. (Interruptions)

SHRI JAGDISH PRASAD MATHUR: I do charge the Government (Interruptions), I do charge the Government. (Interruptions) I don't withdraw. (Interruptions)

SHRI ARVIND GANESH KULKARNI: Sir, the high standards of the Rajya Sabha have to be maintained and this sort of a thing should not be allowed. (Interruptions) I am very sorry, Sir. This kind of a thing the Rajya Sabha has never allowed. (Interruptions) The high standards of the Rajya Sabha have to be maintained.

MR. CHAIRMAN: All right. Everyone, please sit down.

SHRI JAGDISH PRASAD MATHUR: I am charging the

Government and I am not withdrawing. *(Interruptions)* I don't withdraw. *(Interruptions)* I am charging the Government. I am sorry, I cannot agree with Mr. Kulkarni. I am charging the Government *(Interruptions)* ***

SHRI ARVIND GANESH KULKARNI: Sir, this should not be allowed. *(Interruptions)*. You should expunge them from the records. This is not very proper.

MR. CHAIRMAN: I will have to go through the record. *(Interruptions)*.

SHRI JAGDISH PRASAD MATHUR: I am only charging the Government. If imputation is not to be made against the Government, then show me the rule. *(Interruptions)*. Show me the rule. *** *(Interruptions)*.

SHRI ARVIND GANESH KULKARNI: Mr. Mathur, you are welcome to impute motives to the Government, but not to the honourable Members. *(Interruptions)*. You are welcome to impute motives to the Government, but not to the honourable Member, Shri Leon D'Souza. He is an ex-Mayor of Bombay and he is a man of unimpeachable character. *(Interruption')*.

SOME HON. MEMBERS: Yes, yes.

SHRI HARI 'SHANKAR BHABHA: Sir, let me clear my position. I have never imputed any motive to anybody. I only said that the Government is not coming out with clean hands and clear replies. *(Interruptions)*. That is the question. But they are not replying. The Government must be strict. The policy of the Government must be made very clear. This is what I am saying.

***Expunged as ordered by the Chair.

I am not making any imputation. *(Interruptions)*.

DR. RAFIQ ZAKARIA: I don't think this sort of a thing should be allowed to be said any more. *(Interruptions)*. I don't think you should allow him to ask such questions.

SHRI ARVIND GANESH KULKARNI: Sir, what is your ruling? I want your ruling on this.

MR. CHAIRMAN: You want to know my ruling on this? The only ruling that I can think of is that the House is forgetting itself and its duty. We are not proceeding with the questions or with the questions and answers on the Table of the House and I don't think that I can allow this kind of an unseemly wrangle to go on, because it does no good either to you or to the House or to the country and I personally think that I have to go strictly into the record and expunge many things which have been said which, I think, reflect either on this side or on that side because, to me, both sides are the same and nobody shall cast any aspersions either on this side or on that side. I shall remove the whole lot of them. Now, I don't think that we can go on with this question unless we have a drug on hand which will put people to sleep; otherwise, I don't think, this question can be tackled. Now, we will go on to question No. 282.

SHRI R. MOHANARANGAM: Sir, questions No. 282 and 285 are on the same subject. Why don't you put these two questions together?

MR. CHAIRMAN: All right. I will just see. Who is asking question No. 282. I think it is Mr. Gurudev Gupta.

DR. BHAI MAHAVIR: Sir, question No. 285 is in my name

and it concerns the working of the telephones. If you may kindly permit, both these can be taken up together.

MR. CHAIRMAN: All right. I will club them together. Who is asking question No. 282?

SHRI GURUDEV GUPTA: I am asking, Sir.

MR. CHAIRMAN: Who is asking question No. 285?

DR. BHAI MAHAVIR: I am asking question No. 285, Sir.

MR. CHAIRMAN: AU right. Question Nos. 282 and 285.

Functioning of Delhi Telephones

*282. SHRI GURUDEV GUPTA: f
SHRI RAMCHANDRA BHARADWAJ:

Will the Minister of COMMUNICATIONS be pleased to state:

(a-) whether it is a fact that more than 5000 telephones went out of order in Delhi during the first week of March, 1982;

(b) if so; what are the reasons for such failure; and

(c) what steps Government have taken to ensure smooth functioning of the Delhi telephone system?

THE DEPUTY MINISTER IN THE MINISTRY OF COMMUNICATIONS (SHRI VIJAY N. PATIL): (a) Yes Sir.

(b) and (c) A statement is laid on the Table of the House.

fThe question was actually asked on the floor of the House by Shri Gurudev Gupta.

Statement

(b) The main reason has been unusual rain on 28-2-82. and 1-3-82 when a large number of cables became faulty due to seepage of water through the damaged cables.

(c) A number of steps have been initiated to revamp the underground cable system of Delhi through the "Task Force" specially set up. The details in brief are:—

(i) Gas Pressurisation of junction, primary and secondary cables.

(ii) Rehabilitation of the distribution points.

(iii) Rearrangement of jumpers in cabinets and pillars to facilitate quick tracing of faults and to avoid intermittent faults.

(iv) Construction of cable ducts.

Apart from the above works undertaken by the Task Force the following steps are being taken as matter of routine to protect the under ground cable plant.

(i) providing protection to under ground cables by way of half ducts wherever the depth of cable is less than specified.

(ii) Flash testing of cables joints on completion to ensure good workmanship.

(iii) flooding of cable trenches before these are closed to detect damages to the cable if any I a third party.

(iv) patrolling the cable routes to ensure safety to the telephone cables wherever digging is done by other parties.