# RAJYA SABHA

*Monday, the 3rd May, 1982/13 Vaisakha, 1904 (Saka)*

The House met at eleven of the Clock, **Mr. Chairman** in the Chair.

## OBITUARY REFERENCE

MR. CHAIRMAN: I refer with profound sorrow to the passing away of Shri Kanchi Kalyanasundaram, an ex-Member of this House. He was a Member of our House from September, 1969 to April, 1976.

He was born in August, 1909 at Kancheepuram in Tamil Nadu and was a close associate of the late Shri C. N. Annadurai. An active social and political worker, Shri Kalyanasundaram was kept under preventive detention several times. He was a journalist by profession and successfully edited several Tamil language daily newspapers and periodicals during his long journalistic career. He also served as a member of the Press Council of India. Mild-mannered, soft-spoken Shri Kanchi Kalyanasundaram took active part in the debates during his Membership.

We deeply mourn the passing away of Shri Kanchi Kalyanasundaram.

I request Members to rise in their places and observe a minute's silence as a mark of respect to the memory of the deceased.

*(Hon. Members then stood in silence for one minute.)*

MR. CHAIRMADN: Secretary-General will convey to the members of the bereaved family our sense of profound sorrow and deep sympathy.

## ORAL ANSWERS TO QUESTIONS

### Manufacture of Harmful Drugs

*101. SHRI ARVIND GANESH KULKARNI:†

SHRI SURESH SHAMRAO KALMADI:

Will the Minister of PETROLEUM, CHEMICALS AND FERTILIZERS be pleased to state:

(a) whether it is a fact that a number of drugs manufactured by multinationals which are ineffective, out dated and irrational, are being marketed in India;

(b) if so, what steps have been taken by Government to stop manufacturing and selling of such drugs which are harmful to the consumers;

(c) whether any complaints have been received by Government in this regard; and

(d) of so, what action has been taken thereon?

THE MINISTER OF RAILWAYS (SHRI P. C. SETHI): (a) to (d) A Statement is laid on the Table of the Rajya Sabha.

**Statement**

(a) to (d) Criticism has often been voiced that a large number of preparations are being marketed in developing countries some of which are not essential and also have no therapeutic rationale. It was in the light of this criticism that the Drugs consultative committee which is a statutory body constituted under Section 7 of the Drugs and Cosmetics Act undertook an exercise to screen the existing large number of combinations manufactured in the country with a view to banning the manu-

†The question was actually asked on the floor of the House by Shri Arvind Ganesh Kulkarni.

facture and sale of those that were considered to be irrational and unnecessary. The Drugs Consultative Committee had appointed a Sub-Committee which examined 32 groups do fixed dose combinations and took into account the views expressed by the industry, the medical profession and other experts. The recommendations of the Sub-Committee were considered by the Drugs Consultative Committee which recommended that 23 categories of fixed dose combination of drugs may be fully or partially weeded out. As the implementation of these recommendations involved wide repercussions on the industry and the medical profession, the matter was remitted to the Drugs Technical Advisory Board, which is a statutory body under the Drugs & Cosmetics Act to advise the Central and State Governments on technical matters arising out of the administration of the Drugs & Cosmetics Act. The Drugs Technical Advisory Board finally recommended the weeding out fully or partially of 18 categories of fixed dose combinations. These recommendations have been accepted by Government. As licences for manufacture of drugs are granted by the State Drug Control Authorities, necessary instructions for implementing the decisions have been issued to the State Drug Central Authorities. The preparations covered by the 18 categories of combinations recommended to be weeded out are marketed by both multinational drug companies and Indian drug companies.

SHRI ARVIND GANESH KULKARNI: Sir, the statement, which is an exhaustive statement, however, has failed to identify finally which are the categories of combinations. Eighteen—it seems ten is a wrong, typing mistake—have been weeded out in this country in consultation with the recommendations of the Indian Drugs Technical Association or Committee or whatever it is. But, Sir, what we find is that the World Health Organisation has listed many drugs which have been found to be sub-standard and which are particularly used in the third world countries or what you call weaker countries. Sir, in this connection, first I want to know from him what are the finally agreed drugs by the Drugs Technical Advisory Board, what are their names, so that they should be widely published to come to the notice of the people? Sir, in this connection also, may I draw to his attention the latest coverage in the "SUNDAY" which says that 1.7 million children are going to die this year in the whole world, out of which the share of the third world countries is naturally more? They say that Orasecron Forte manufactured by Nicholas and marketed by multinationals as well as E. P. Forte manufactured by UNICHEM are harmful. So, Sir, I want to know, whether the Government, in view of the grave dangers to the children in this country, have made any attempt to include these drugs in the finally listed 18 drugs. And in this connection also, I want to know how many MNCs out of these—because the reply given is vague; it includes MNCs and Indian drugs manufacturers also are there—are indulging in anti-social acts, what are their names, of MNCs as well as Indian drugs manufacturers, and what steps the Government propose to take against the MNCs as well as Indian drugs manufacturers, which are participating in these nefarious, grave crimes against humanity?

SHRI P. C. SETHI: When criticism was voiced against certain manufacturers' items, then the Drugs Consultative Committee took up the matter, and they identified 23 cases or categories which they recommended should be partially or completely weeded out. Ultimately, the matter was subjected to a decision of the Drugs Technical Advisory Board, and the Drugs Technical Advisory Board recommended that 18 combinations should be weeded out. Sir, I am now

reading these combinations as suggested by the hon. Member.

MR. CHAIRMAN: Would you like to have them privately?

SHRI ARVIND GANESH KULKARNI: He can place the list on the Table of the House.

MR. CHAIRMAN: Please place it on the Table of the House.

SHRI ARVIND GANESH KULKARNI: I have only desired that it should be published in the interest of consumers.

MR. CHAIRMAN: I know.

SHRI P. C. SETHI: I would place it on the Table of the House.

MR. CHAIRMAN: Any specially dangerous drug you might mention, specially highly toxic or any such...

SHRI P. C. SETHI: To cite an example, I will name two or three, and then place the list on the Table of the House.

SHRI ARVIND GANESH KULKARNI: And publish also.

SHRI P. C. SETHI: I will pass on one copy to him so that he can help me in getting this published. (*Interruptions*).

SHRI ARVIND GANESH KULKARNI: Why don't you pass it on to the authority on your left, which is the proper authority?

MR. CHAIRMAN: Why not behind you, Mr. Kulkarni? There is somebody there. (*Interruptions*) I think it would be best if one of the hon. Members is given a copy. (*Interruptions*).

SHRI P C. SETHI: Out of 18, some are: Fixed dose combinations—Amidopyrine, Atropinein, analgesics, strychine and caffein, yohimfine, bromide, I am placing the statement on the Table of the House. [*See* Appendix CXXII, Annexure No. 17]. The hon. Member has also asked me, Sir, as to how many formulations are marketed by multi-nationals.

There are approximately 350 formulations out of which 44 formulations are by the multinationals. Eight are made by the public sector undertakings. And the rest are made by Indian manufacturers. In regard to these also, because the State Government is the authority to exercise the powers under the Drug Control Act and implement the provisions of the Drug Control Act, information is passed on to them and a cut-out date for the stoppage of manufacture of these items has been given to them, sometime in September, 1982 and for marketing, six months later, sometime in March, 1983

SHRI ARVIND GANESH KULKARNI: what about the drugs I mentioned, in regard to the children? Sir, my second question is yet to come. But one part of my first question has ont been answered. I mentioned about the 1.7 million children...

MR. CHAIRMAN: Who will die in the world.

SHRI ARVIND GANESH KULKARNI: Because of the marketing of these two drugs. The question is, whether they are also marketed in India and what steps Government propose to take?

SHRI P C. SETHI: The hon. Member will prefer to find out from the list which I am submitting. As far as the question of marketing of these drugs in other countries is concerned, the World Health Organisation has gone into it. From time to time, they go into this problem. They have also forwarded names of about eighteen drugs which have been banned in some countries.

SHRI ARVIND GANESH KULKARNI: Sir, at the outset, I am sorry to say that the hon. Minister has put the responsibility on me to find out. I am bringing this to his notice. He is an expert. He knows. His department officers are there. He could have said whether this is marketed or not. This is a simple question.

MR CHAIRMAN: They are going into it more deeply.

SHRI P. C. SETHI: Sir, the Deputy Health Minister, Miss Kumudben Joshi, has come to my rescue.

MR. CHAIRMAN: This is really supposed to go to the Health Ministry. Mr. Sethi is answering gallantly for the lady Minister.

SHRI P. C. SETHI: For a drug for hepatitis disturbances permission to manufacture has been refused in 1978.

SHRI ARVIND GANESH KULKARNI: There is one other thing which I would like to know from the hon. Minister of Petroleum Chemicals. He is here, answering questions, on behalf of the Minister of Petroleum and Chemicals and not on behalf of the Health Minister. I would like to know from him, whether an item has been brought to his notice, particularly the study made by the Indian Institute of Public Administration very recently. A very exhaustive study has been made on the working of multi-nationals in the country and I would like to krow whether any steps have been taken by the Ministry of Petroleum and Chemicals on the basis of this study. In this House, we have mentioned many of these names and the affidavits filed by the Government themselves before the High Court of Delhi in the case of these multi-nationals. In this connection, I would like to know whether this study has been brought to his notice and whether he is aware that these foreign drug companies, by using various methods, are indulging in profit-making and sending them abroad. I would also like to know, in this connection, whether Governemnt has taken any final decision. When he was the Minister of Petroleum and Chemicals, he said that this would be coming very soon. Now, he has gone to the Railways. Mr. Shiv Shankar is here. My question is, in regard to these multi-national drug companies, which are indulging in profiteering and which are hiking the prices of the medicines by various methods, whether any steps are going to be taken by the Government and what does he mean by 'very soon'?

SHRI P. C. SETHI: As far as the price rise is concerned, there is a separate question, which would come later on. No price rise has been made by any company without the BICP clearance. BICP clearance has been given in the case of many drugs and as far as the other question of foreign equity of the companies is concerned, it is also to be reduced to various levels. For example, in the case of Uni-Sankyo, from 49 to 40 per cent, E. Merck, from 60 to 40 per cent, Glaxo, from 75 to 40 per cent and so on; in the case of Parke Davis from 83 to 40 per cent, Warner Hindustan, from 50.3 to 40 per cent and May and Baker, from 60 to 40 per cent.

MR. CHAIRMAN: All these will be brought down to 40 per cent?

SHRI P. C. SETHI: Foreign equity to 40 per cent. The Reserve Bank of India has initiated action in these cases. Action is being taken to reduce their equity.

SHRI SURESH SHAMRAO KALMADI: Sir, many multi-nationals prefer Government hospitals for unloading their products because the drugs can be sold in huge quantities and consumed by them without anybody bothering about the quality. With the connivance of the Administration and hospitals and an obsolete system of purchasing drugs by large inflated quotations, this racket flourishes. The different kinds of tablets, capsules and injections run to over 3,000 and

not even 100 of them are tested annually. The Drug and Cosmetics Act exists only in name. In 1978-79, there was one prosecution and he was let off with a fine of Rs. 1500. In 1979-80, there were four prosecutions and they were let off lightly, and in 1980-81, there was one prosecution and he was acquitted. Some more deterrent punishments have been announced by the Ministry lately. But, I feel, there is no will on the part of the Government to implement this Act. Sir, before I go on to the question which I have to ask, I would only like to narrate one incident of a leading intellectual of this country who was being treated in a public hospital and he went to Amsterdam and immediately he had to be taken to a hospital. When the doctor saw the list of medicines prescribed of various multi-nationals in this country, he told the patient, 'I am surprised to see you alive. Some of those medicines have been used on cattle but some have not yet been used on them'. Well, this is the type of products which are being dumped by multi-nationals. My question to the hon. Minister would be: Is the Government thinking of any such squad of Drug Inspectors exclusively to check the quality in public Hospitals? Is there any proposal for effective drug control administration which has adequate prosecution power functioning independently of the Health Ministry?

SHRI P. C. SETHI: Sir, as far as drug manufacture is concerned, although the licences are issued in consultation with the Health Ministry by the Ministry of Petroleum and Chemicals, yet, Sir, there are specific conditions laid down for this. And as far as these conditions are concerned, the Drug Controller at the Centre and the State Drug Controllers have to check the therapeutic and prophylactic qualities to be determined in relation with the claims and conditions for which the medicines are recommended. And they are also to be tested for the contents of vehicles excepients, additives and pharmaceutical aids. The very fact that the Drug Controllers are active at the Centre and in the States shows that it is not possible that the medicines which are produced in the country are all of the variety, as the hon. Member has pointed out as being mentioned to some intellectual person in Amsterdam.

MR. CHAIRMAN: It proved that we are very tough people. Even with poison we can live.

SHRI P. C. SETHI: Sir, recently, the Health Ministry has introduced an amendment to the Drug and Cosmetics Act, and it has been introduced in the House. Once it is passed, the Centre will acquire powers to stop manufacture of any medicine...

SHRI SURESH SHAMRAO KALMADI: Why was there no prosecution at all?

MR. CHAIRMAN: It does not really arise from this. They will need information collection.

SHRI SURESH SHAMRAO KALHADI: Sir, this is the topic of harmful drugs. There are no prosecutions for the last three or four years.

MR. CHAIRMAN: You have given a list of three or four. But they will probably want a little notice for that.

SHRI P. C. SETHI: Sir, it should be collected and compiled from various States because the Drug Controllers at the States are the authority to prosecute.

MR. CHAIRMAN: It will be a long list.

DR. M. M. S. SIDDHU: Sir, I may at the outset request that in India there is no drug adverse affect-monitoring done and that should be done. We are all dependent upon the adverse effect of the drugs which have been found either in western countries or in Japan or by the WHO. We do not have any machinery of our own though it is very desirable to have it. Sir, I would now come to the irrational formulations. The Drug and Cosmetics Act lays down patent and

proprietory medicines containing vitamins, prophylactic, theraputic or for children's use. The vitamins shall be in the quantity not less and not more than that. This has been very well brought out by the Drug & Cosmetic Act, page 398, under rule 124(b). Schedule V. This notification was published on July 13, 1978.

MR. CHAIRMAN: Dr. Siddhu, I may inform you that this notification was before me for opinion. You are probably going to read "not more than three thousand and not less than five thousand". Is that what you are going to read?

DR. M. M. S. SIDDHU: The question is that this notification prescribes the dosage of vitamins A, B1, B6, B12, C, D....

MR. CHAIRMAN: That notification, I think, has been withdrawn now.

DR. M. M. S. SIDDHU: No, Sir. It is still there.

MR. CHAIRMAN: All right, Mr. Sethi will tell us.

DR. M. M. S. SIDDHU: The only thing is that it has not been acted upon. The reasons I will not go into. It is for them to tell us the reasons. I know some of the reasons.

MR. CHAIRMAN: I was the person who gave opinion against that notification, I remember, before I came here. (*Interruptions*).

DR. M. M. S. SIDDHU: This irrational overdosage of vitamins has lead to...

MR. CHAIRMAN: If you read that notification, for an infant under eight months — 10,000 units; for an adult 100 units.

DR. M. M. S. SIDDHU: Yes, Sir.

MR. CHAIRMAN: The first one is for not less than 5,000 and not more than 3,000. I mean this is the first item. I remember that.

SHRI ARVIND GANESH KULKARNI: Sir, it seems that you are also a medical doctor here.

MR. CHAIRMAN: I was only a lawyer then giving consultation. This notification, I thought, was withdrawn after I gave the opinion.

DR. M. M. S. SIDDHU: No Sir; as far as I know. Sir, I may now come to the question of overdosage of vitamins which leads to a strain on the body. Either it is excreted or metabolised and only some quantity is retained by the body. But, unfortunately, Sir, there is a large number of drugs manufactured which contain a very high dosage, for instance. Becosule, Becozyme Forte, Betron, Becolex, Cobadex etc.

MR. CHAIRMAN: Will you now formulate the question?

DR. M. M. S. SIDDHU: Sir, the question that arises is that some of the overdosage of vitamins is harmful and what has been prescribed therapeutically is that there should not be any overdosage to children, adults or to anyone. So, why has the Government not acted upon it? That is my first question. And, secondly, by when will they see that the dosage as recommended is enforced?

MR. CHAIRMAN: I think you better look into that notification

SHRI P. C. SETHI: Sir, I think your valued opinion may be one of the reasons. However, I would like to add, Sir, that there have been some representations from the drug manufacturers regarding the mark-ups to be allowed in such vitamin formulations. The Government are considering these representations and once a decision is taken on the mark-ups, the re-formulated vitamine could be issued.

MR. CHAIRMAN: The figures are patently wrongly printed in the notification.

DR. M M.S. SIDDHU: This is the very reason that the pre-structure of vitamins has not been determined with the result that the multi-nationals and other national drug companies are producing these drugs for the last two years.

---

## WELCOME TO HIS EXCELLENCY DR. WAHID ALI, PRESIDENT OF THE SENATE OF TRINIDAD AND TOBAGO

MR. CHAIRMAN: I will interrupt the proceedings of the House for a minute. I have an announcement to make.

We have with us this morning, seated in the Special Box, His Excellency Dr. Wahid Ali, President of the Senate of Trinidad and Tobago who is on a visit to India from the 30th April to the 8th May, 1982, on our invitation. A graduate in Medicine, Dr Ali is no new comer to National Office, in that he was a Chairman of the National Youth Council of Trinidad and Tobago a Senior Vice-President of the World Assembly of Youth; President of the Regional Union of West Indian Students and the International student Conference (University) Switzerland 1960; Quebec, Canada, 1962. Dr. Ali is a member of the executive Committee of the Anjuman Sunnat-ul-Jamaat Association Inc. and President of the Inter-Religious Organisation. He entered the Senate in 1970 as a member of the Government team and one year later, was appointed President.

On behalf of the Members of the House and on my own behalf, I take pleasure in extending a very hearty welcome to Dr. Ali and wish our distinguished guest a very enjoyable and fruitful stay in our country. We hope that by the time he leaves us, he would have seen and learnt more about our country and our people. Through him we convey our greetings and best wishes to the Senate and the friendly people of Trinidad and Tobago.

## ORAL ANSWERS TO QUESTIONS— contd.

DR. M M. S. SIDDHU: Sir, decision with regard to mark-up has been pending since 1978; that means, four years. I would like to know as to when they will decide the mark-up of these vitamins so that law is enforced.

MR. CHAIRMAN: How soon will you do it?

SHRI ARVIND GANESH KULKARNI: That is a million-dollar question.

SHRI P. C. SETHI: I will pass on the question, to the Ministry to be dealt with as early as possible.

MR. CHAIRMAN: Mr. Shiv Shankar will be informed by you We now pass on to the next question.

*102. The questioner (Shri Jagdish Prasad Mathur) was absent for answer vide col. 33 . . .infra.

### कम्पनी कानून के उपबंधों का उल्लघंन

*103. श्री हुक्मदेव नारायण यादव : क्या विधि, न्याय और कम्पनी कार्य मंत्री 15 मार्च, 1982 को राज्य सभा में अतारांकित प्रश्न 1656 के दिये गये उत्तर को देखेंगे और यह बताने की कृपा करेंगे कि :

(क) 31 मार्च, 1981 तक जिन 2520 कम्पनियों के विरूद्ध 4049 मामले अनिर्णीत थे उनमें जल्दी से फैसला कराने के संबंध में क्या कार्यवाही की जा रही है ; और

(ख) 31 मार्च, 1981 के बा मार्च, 1982 तक कितने मामले पकड़े ग और उन्हें निपटाने के लिये क्या कार्यवाह की जा रही है ?