

17.29 hrs.

HALF-AN-HOUR DISCUSSION

Carcinogenic Chemicals in baby products

SHRI ANIL BASU (ARAMBAGH): Sir, this Half-an-hour Discussion arises out of the answer given by the hon. Minister of Health and Family Welfare on 20.04.2005 to Starred Question No.362 regarding Carcinogenic Chemicals in Baby Products.

The issue is not only of baby products but the issue is more wider. The problem is of great importance. It not only concerns our babies but it also concerns the health of the whole population of our country. In 1940, when the country was under British Rule, the Drug Control Act was enacted. It was called Drugs and Cosmetics Act, 1940 and during that period, you are well aware that our indigenous capability to manufacture and produce drugs and cosmetics was very limited. Most of the drugs and cosmetics were imported. In the Act of 1940, the provisions were made to take care of the imported drugs and cosmetics so that spurious drugs and cosmetics did not come to our country. After that, in subsequent amendments some provisions were amended but the same provision is continuing till today in respect of Section which deals with the spurious and fake drugs.

17.32 hrs.

(Shri Balasaheb Vikhe Patil *in the Chair*)

In these 57 years of our Independence, our indigenous pharmaceuticals and drug industry have grown to a large extent. With the advance of science and technology, side-by-side manufacturing of spurious drugs, fake drugs and baby products had also increased manifold. In recent media reports, it has been stated that the spurious drugs market in our country is worth around Rs.4000 crore annually. In Delhi alone, the spurious drugs manufactured in Bhagirath Palace are worth more than Rs.2000 crore annually. The problem is very serious. I know today we are discussing carcinogenic chemicals in baby products. But it is a very small part of the whole issue. I would come to this specific question which is going to be discussed here. It is a matter of great

concern for the country. You will be surprised to know that not a single manufacturer of spurious drugs or baby products could be punished in the last 57 years under this Act.

Not one single person could be imprisoned on this ground. Why was it so? Even though there is a legislation on this and the State Drug Control Department has conducted so many raids in different places, yet nothing could be proved before a law and there was no conviction. Now, the question arises - is there any lacunae in the law?

In the reply given by the hon. Minister in response to a supplementary question that I asked on the 20th April, he used two very intelligent words, namely, 'unsafe' and 'not harmful'. In the Act, Section 17 (a), (b) and (c) defines spurious drugs, adulterated drugs and misbranded cosmetics. Section 27 (a) of the Act empowers the Government and the investigating agencies for meting out punishment to the persons or organisations involved in dealing with such things. What does this Section say? It says:

"Any drug likely to cause death or likely to cause such harm on his body as to amount to grievous hurt within the meaning of Section 320 of the Indian Penal Code solely on account of such drugs."

It means that even if the drug is spurious, or the cosmetics is spurious, unless it does not cause death, the person involved in selling such drugs is not liable to be punished.

THE MINISTER OF HEALTH AND FAMILY WELFARE (DR. ANBUMANI RAMADOSS) : You may kindly be specific. Is it drugs or cosmetics?

SHRI ANIL BASU : Sir, the Act is one - The Drugs and the Cosmetics Act.

Sir, the penal provisions are contained in Section 27 (a) of the Act.

DR. ANBUMANI RAMADOSS: The subject under discussion today is only cosmetics.

MR. CHAIRMAN : If you limit your discussion to the subject, then only it would be possible for us to complete the discussion within 30 to 35 minutes. Otherwise, it would be difficult for the hon. Minister also.

SHRI ANIL BASU : Sir, I am only trying to draw the attention of the House to the penal provisions that are contained in Section 27 (a) of the Act which empowers the Government to penalise a person who is engaged in this trade. The provision says that until and unless it causes death or grievous injury, as defined in Section 320 of IPC, it is not punishable. It is for this reason that during the last 57 years, though hundreds and thousands of raids were conducted by the Drugs Controllers of the States, not one single case has found conviction and no one could be punished.

MR. CHAIRMAN: Drugs is a very large area.

SHRI ANIL BASU : Sir, I am combining both - drugs and cosmetics.

MR. CHAIRMAN: Spurious cosmetics is the issue here.

SHRI ANIL BASU : The issue here arises out of a baby product of a global company. On the label of the product the company claims that the growth of a baby is guaranteed if that specific oil was used by way of a massage to a baby. Now, in Section 17 (c) of the Drugs and Cosmetics Act, it has been stated that if the label or container accompanying the cosmetics bears a statement which is false or misleading, then either the reply given by the Minister is false, or the statement on the label of the container is false.

What is the relief which we can provide to the people of our country? The Government constituted a committee under the Chairmanship of Dr. Mashelkar. That committee submitted its report to the Government in the year 2003. But only discussions are going on for the last two years and the Government could not bring in any amendment to the law. Sir, since 1982, we have not been able to charge any offender under this section because in 1982, the Act was amended. Earlier, it was three years imprisonment. By the amendment of 1982, the three years imprisonment was increased to life imprisonment. But we have not been able to charge any offender under this section to life imprisonment because it was not possible to connect the death of a person to drugs and cosmetics manufacture. It is very difficult or it is the failure of the investigating agencies to control manufacture and marketing of spurious drugs and cosmetics because there is a lacuna in the law.

My question to the hon. Minister is this. How are you going to make the law effective so that it can serve the purpose for which it was enacted? How can the products be safely used for our babies? Many companies are now engaged in the manufacture of baby products. But the law itself is not strong enough to punish the offenders.

The report of Dr. Mashelkar Committee has suggested how to make the punishment more stringent. Death penalty has been recommended. My apprehension is, even if Government accepts the recommendation of death penalty, the question still remains as to how and under what law is the Government going to give that punishment to the offenders. It is because the main section which deals with the punishment lacks necessary amendments to prevent the manufacturers from manufacturing and marketing spurious drugs and cosmetics. From our experience of 57 years, it has been proved that production and marketing of spurious drugs and cosmetics are increasing every year. We will not be able to prevent it unless and until the law itself is amended and the specific section is made to empower the investigating agencies to investigate the cases in a proper manner and prove their case before the court of law. Such an

amendment should be incorporated in the law itself. In the absence of that, whatever stringent punishment would be recommended will only be an eyewash.

It will provide relief neither to the pharmaceutical or cosmetic industry nor to the people or babies of this country. My main question to the Government is this: How are you going to plug this loophole in the Act?

MR. CHAIRMAN : Shri Varkala Radhakrishnan, please ask only questions. You are a learned and experienced Member.

SHRI VARKALA RADHAKRISHNAN (CHIRAYINKIL): Sir, I was closely listening to my friend's argument. Now, I would make a suggestion to the Minister concerned.

So far as I understand, till today there is no substitute for mother's milk. Breast feeding is the effective remedy. To my knowledge, there is no substitute for mother's milk. The tendency now-a-days is, immediately after delivery, young mothers are eager to put on the brassieres and prevent breast feeding. Would the Minister be pleased to make a countrywide campaign for encouraging breast feeding because it is a cure for even breast cancer? It is reported that because the breast feeding is not taking place, mothers suffer from cancer in their old age. So, in order to prevent cancer, please make a countrywide campaign among young mothers so that after delivery they should go in for breast feeding. You persuade them to go in for breast feeding through an awareness campaign.

In the meanwhile, rural poor women must be given nourishing food. Then only it is possible. Food must be supplied to the poor and new young mothers for taking recourse to breast feeding. This is the only remedy. Otherwise, children will become victims to chemically adulterated baby food. You are in the habit of doing many good things. You can launch a countrywide campaign also for encouraging breast feeding.

MR. CHAIRMAN: Shri Radhakrishnan, kindly cooperate.

SHRI VARKALA RADHAKRISHNAN : That is the only remedy.

DR. CHINTA MOHAN (TIRUPATI): Sir, some newspapers have reported that these baby products are carcinogenic. We have gone through the Minister's reply. How is he going to remove the apprehension from the minds of the people that these products are not carcinogenic?

श्री शैलेन्द्र कुमार : सभापति महोदय, माननीय श्री अनिल कुमार बसु जी ने कार्सिनोजेनिक रसायन के बारे में बहुत महत्वपूर्ण सवाल उठाए हैं । जितने भी सिन्थेटिक दूध, जूस या फॉस्ट फूड के नाम पर पीजा या बर्गर हैं या बच्चों के लिए पैकेट बंद सामान हैं, इनके विज्ञापन में कंपनी वाले दिखाते हैं कि इसे बच्चों को खिलाइए या पिलाइए या तेल मालिश कीजिए, इससे बच्चा बलवान होगा, स्वस्थ होगा। लेकिन इनके पीछे की वास्तविकता कुछ और ही होती है। इस प्रकार की कार्सिनोजेनिक वस्तुएं जो बच्चों के लिए बनाई जा रही हैं, क्या उनकी जांच माननीय मंत्री जी करवाएंगे? ऐसी बहुत सी कंपनियां हैं जो बच्चों के उत्पाद बनाती हैं, जैसे जानसन एंड जानसन, सनफार्मा, डाबर इंडिया लिमिटेड इत्यादि। मैं माननीय मंत्री जी से इस विषय में यह जानना चाहूंगा कि ऐसी कंपनियों के उत्पादों की जांच कराने और इनके खिलाफ न्यायिक कार्यवाही करेंगे, क्योंकि इनके बहुत से उत्पाद बच्चों के स्वास्थ्य पर हानिकारक प्रभाव डाल रहे हैं।

DR. ANBUMANI RAMADOSS: Sir, I share the concerns of hon. Member, Shri Basu. Probably, it is the second time that he is asking the same question. I think, he is not satisfied with my last reply that I had given to him. Today, we are going through a Half-an-Hour-Discussion on the Carcinogenicity of Cosmetics. Sir, I share the concerns of the hon. Member, Shri Basu that the cosmetics have not only got to do with the babies but also with the general population of the country. He also said that not a single manufacturer of spurious drugs or cosmetics have been punished. This is not true. There have been innumerable instances where they have punished; they have been recommended life imprisonment; and a lot of fine was there. I would bring to the notice of the hon. Member a lot of cases, that is, a list of how many people have been convicted and how many prosecuted.

MR. CHAIRMAN : Kindly table the list, as it will be helpful for all the Members.

DR. ANBUMANI RAMADOSS : I will inform the House through you, Sir. Even though both the issues are serious issues - the drugs as well as the cosmetics issues - today we are taking up the issue of cosmetics only. But, nevertheless, I could understand the concern of the hon. Member about drugs, the so-called spurious drugs and the activities going on in the country. The Government has taken a lot of steps recently to curb this practice of both the spurious as well as the mis-branded cosmetics. Even though the question is regarding cosmetics, I will go into first the question of drugs. I would like to answer a part related to drugs' question also and about his query regarding the Mashelkar Committee's recommendation, which was mostly on spurious drugs.

The Committee was formed under Dr. Mashelkar to go into the issues of spurious drugs. He had given a comprehensive recommendation, and a part recommendation was taken up. Only the penal provisions, the legal provisions, were taken up at that point of time and were introduced in the 13th Lok Sabha. We are into the 14th Lok Sabha. Again, we have taken up the issue. We have taken up

some of the recommendations of Mashelkar Committee, for example, having more stringent legislation, making the offences cognizable and so on. Previously, they were not cognizable. Now, we are making the offences cognizable.

MR. CHAIRMAN: It is fine.

DR. ANBUMANI RAMADOSS : We are increasing the fine. It will be a hefty fine. Previously, it was about Rs. 10,000. Now, we are going to increase it to about Rs. 10 lakh.

Then, the hon. Member asked about the capital punishment. Again, this has been deliberated in the Cabinet meeting. The Cabinet wanted some other recommendations also into that. So, it has gone back to the Law Ministry for redrafting. When it comes from the Law Ministry, we will take it to the Cabinet. Then, I am sure, we will deliberate a lot in both the Houses. We will pass on more stringent laws to curb these spurious drugs as well as cosmetics. We are very serious about the Mashelkar's recommendations. Now, the Member may ask how the Government is doing to curb this practice. We are going through a phase of capacity building where we are investing roughly Rs. 350 crore, both for food as well as drug regulatory bodies. We are modernising and improving literally about 20 Central and State Drug Labs across the country. Sir, on an average, 35,000 products are tested every year. They are tested randomly. But, we need to increase it to 100,000 minimum so as to go into the intricacies of these spurious drugs. We need first the labs to be modernised according to the international regulation. So, we are modernising them. We are imparting training to our drug inspectors, State drug controllers and a lot of training programmes are already been going on. We are all centralising the system of connectivity from the State Drug Controlling Authority to Central Drug Controller Authority. A lot of activities are going on to have this. In due course of time, once all this apparatus is inserted, modernisation is done and the people are properly trained, things will improve. Of course, we are having a Food and Drug Administration Bhavan.

I laid the foundation-stone about two months ago. It will be completed in another 15 months, by next year, whereby they are going to have a separate authority or a separate body to control and regulate both the food as well as drug industry in the country. It is going to be a multi-storeyed building where all these facilities are going to be put. In fact, we have written to the Expenditure Department to increase our manpower resources in that authority and body. Ultimately, our aim is to have an independent authority for drugs. This has nothing to do with the Government. It is on the lines of the Telecom Regulatory Authority of India. Like that, we need to have an independent authority for drugs and cosmetics to regulate the whole industry because the industry is growing at a very rapid pace. We need to regulate it and make it transparent, to have quality. It is so because, today, the pharmaceutical industry is the fourth biggest in the world. We are a little behind regulating the growth. We are going to do all these things for improving drugs and checking the misuse and spurious drugs.

Coming back to cosmetics, I would like to say that the Cosmetics Act was amended in 1962. But since then a lot of cosmetic products have come into the country. Internationally, you can see that every day newer products of cosmetics are coming in. The Government have taken steps to regulate the cosmetics because every product which is used, like a tooth-paste or a hair oil or a skin lotion or a soap or a shampoo, is a cosmetic today. Every day, advertisements are coming out for newer products. So, the Government is serious about regulating these products. Safety of the citizens is our prime concern. We have a system whereby on the one hand we say what should be used in the cosmetics. In the case of tooth-paste, we have a general formulation that the percentage of this product should be this, soap should have a certain quantity of chemicals in this and like that. So, we have a system. On the other hand, we have another system of chemicals or drugs, the ingredients of which should not be used in these cosmetics including baby cosmetics. So, that is a more important thing.

Literally, we have about 28 cosmetic products as a whole like the baby powder. This is one product. Like that, we have 28 products. We say what are

the ingredients which should not be used, which are detrimental to the health of the baby, health of an adult or of a citizen. So, we have clearly drawn clear-cut parameters of the cosmetic industry. We are looking very closely at that. But even then, after going through all these also, there are some issues which have been raised by the FDA Commissioner in Maharashtra after which the question had come up. He had served notice to a couple of companies asking them about their claims. When we had asked him as to what was going on, he said that at no point of time, when he asked them, had anything been mentioned about carcinogenicity in that. So, today, there is no issue of carcinogenicity because we have regulations as to what products are to be used and what not to be used. In the case of all these products, there is no question of carcinogenicity as on date. It is literally not possible for the Government to test each and every product for carcinogenicity because we have hundreds of thousands of cosmetic products. We do not have resources to test it for carcinogenicity.

MR. CHAIRMAN : The point is that prior to coming into the market, it should have been approved by some authority.

DR. ANBUMANUI RAMDOSS: Yes, the State Drug Controller approves these products going into the merits and demerits of what are the ingredients to be used and not to be used

Now, after all these issues have come up, we have set up, in the month of June, the Drug Consultative Committee. It is a Committee consisting of all the State Drug Controlling Authorities in the country. They will all assemble together under the Drug Controller General of India. They are going to deliberate certain issues which have been raised by the hon. Members of this House.

About making frivolous claims, about the labelling pattern, I would say that some hon. Members have brought out the issues. They said how some claims are made. For example, there is the claim saying that you can change your colour from black to white in a couple of days. In some, they say that it is clinically proven that the baby could grow to this extent. So, all these claims are there. Therefore, in future, after the Drug Consultative Committee has been set up, they will give their recommendations to the Drug Technical Advisory Board (DTAB), which is the highest Authority in the country today.

18.00 hrs.

The DTAB will recommend to the Government what are the recommendations and how to regulate schemes. This is the need of the hour today. It is because there are so many claims, which go out and they have to be scientifically validated. Hon. Member was right in saying that in America, no such claims are there in their baby products but in India, some of the baby products have these claims.

MR. CHAIRMAN : Just a second. After completion of the Minister's reply, we can extend the House for 5 - 6 minutes.

DR. ANBUMANI RAMADOSS: In different developed countries, they have one parameter. Some of the countries have different parameters of claims. So, we need to regulate all that and we are going to. (*Interruptions*)

SHRI ANIL BASU : The main concern is that the companies while doing business in their own country are not using the same level which they are using here. It is because this company still considers itself as a native.

MR. CHAIRMAN: The Minister is trying to explain how to renew regulating authority.

DR. ANBUMANI RAMADOSS: That is why we are going into all those things.

MR. CHAIRMAN: You mean to say that you are going to use global standards.

DR. ANBUMANI RAMADOSS: That is exactly what we are going to do. Currently, we are having a global standard as far as Drug Controlling Authority is concerned.

MR. CHAIRMAN: You are going to monitor it very closely.

DR. ANBUMANI RAMADOSS: Today our standards are based on European Economic Community standards, and directives. Then, we have the Cosmetics Toiletries and Fragrance Association (CTFA), USA. We have guidelines of International Fragrance Association (IFRA) updated from time to time. We are going through all these standards. Again, after these deliberations which DCA will have, we are going to have firstly, claims and secondly, the contents of the cosmetics. So, today the law states that only the main ingredients need to be printed on the label of the products. But, after these deliberations, we are trying that all the contents should be mentioned on the cosmetic products in the descending order. We are going to take up these issues, and also the so-called frivolous claims. If there is a claim, they have to clinically prove those claims. Without this, they cannot mention those claims and call it as a baby product or a gender product or a woman product or an aging product and so on. Whatever they claim, they have to be clinically proved and then they have to mention it. We are going through a process of regulating it. One part of regulating it does not mean having the inspector-raj into the system. As a growing industry, we need to look at the industry as a viable growth for the economy. We need that quality should be infused into the system. That is why we are going in for regulating all the cosmetics.

MR. CHAIRMAN: I would like to know whether Government is going to compel them to print all this.

DR. ANBUMANI RAMADOSS: Yes, Sir. We are going to do that. It is the question of time before we bring that. Now, I will come to Hon. Member, Shri Radhakrishnan's query of mother's breast-feeding.

MR. CHAIRMAN: It should come from the mothers' side.

DR. ANBUMANI RAMADOSS: I am with you and this is a very pertinent question asked by him, even though this does not relate to the question directly. Today, more and more modern mothers are not feeding their babies due to other modern concepts and modern thoughts. But, the mother's milk - the first after the

new born - is the best anti-biotic ever produced for the newly born baby. There is a study in Chhattisgarh where the infant mortality rate is not that high compared to the other areas, other tribal areas and our own surrounding areas. It was because we find that all the children were compulsorily mother-fed. That is why there was a slight decrease in infant mortality rate. That is one of the better studies. Even though this propagating of the mother's milk relates to both Department of Women and Child Development in the HRD Ministry and the Health Ministry, we have different schemes for the mothers, and to be mothers also. For pregnant women, the Health Ministry gives micro nutrients, the Department of Women and Child Development gives macro nutrients. They give protein, rice etc., we give micro nutrients, we have to increase the capacity and nutritional status of the mothers and to be mothers. They are taking a lot of steps, we are taking a lot of steps and we are propagating this. *(Interruptions)*

SHRI VARKALA RADHAKRISHNAN : They should come forward.

DR. ANBUMANI RAMADOSS: This is one of our priorities and we need to bring down the infant mortality rate.

SHRI VARKALA RADHAKRISHNAN : More diseases are being attracted by tying it around the breasts. *(Interruptions)* It is because the brassiere companies are very eager to sell their brassieres. They will sell them abundantly. *(Interruptions)*

MR. CHAIRMAN: He has already replied this.

. *(Interruptions)*

DR. ANBUMANI RAMADOSS: To sum up everything we are very concerned about both drugs, as well as, cosmetics. We are taking all steps to prevent the misuse of the cosmetics and the drugs. Thank you. *(Interruptions)*

MR. CHAIRMAN: Thank you. The House stands adjourned to meet tomorrow, 10th May, 2005 at 11.00 a.m.

18.05 hrs.

*The Lok Sabha then adjourned till Eleven of the Clock
on Tuesday, May 10, 2005 / Vaisakha 20, 1927 (Saka).*
