

# RAJYA SABHA

Wednesday, the 5th March, 1986/14  
Phalguna 1907 (Saka)

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

## ORAL ANSWERS TO QUESTIONS

### Harmful effect of clioquinol drugs

\*141. SHRI NAND KISHORE BHATT:†

DR. JOSEPH LEON D'SOUZA:

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

(a) whether Government's attention has been drawn to the news item published in the Telegraph Calcutta of 23rd November, 1985 under the caption "Harmful drugs for diarrhoea";

(b) whether it is a fact that high incidence of blindness and paralysis have been detected due to the consumption of clioquinol drugs in several countries including India;

(c) whether it is a fact that the use of hydroxyquinoline class of compounds was banned in our country;

(d) whether it is also a fact that medicines containing clioquinol such as Amebiotic, Amiclint, Chlorambin, Dystar, Saril are still being marketed in the country;

(e) whether it is also a fact that the Ciba Giegy have withdrawn their medicines containing clioquinol compound; and

(f) if so, what are the reasons that other companies have not yet withdrawn the marketing of such drugs and what remedial action Government have taken in the matter?

†The question was actually asked on the floor of the House by Shri Nand Kishore Bhatt.

THE DEPUTY MINISTER IN THE DEPARTMENT OF FAMILY WELFARE (SHRI KRISHNA KUMAR):

(a) Yes, Sir.

(b) According to information available no incidence of blindness or paralysis due to the consumption of clioquinol has been reported in India.

(c) No, Sir.

(d) Yes, Sir.

(e) Yes, Sir.

(f) On the advice of the medical experts, manufacture and marketing of drugs containing clioquinol has not been prohibited.

SHRI NAND KISHORE BHATT: Sir, the well-known drugs, Mexaform, Enterovioform, Enterokinol and Dequinol, are examples of the Hydroxyquinoline class of compounds. These drugs have been extensively used in the treatment of diarrhoea diseases for the last 40 years.

Sir, in countries like Japan and Nigeria a number of cases have been found in which the effects of these drugs have been very dangerous, people have become blind, there have been also reports of effects of paralysis.

Under these circumstances, Sir, I would like to know from the hon. Minister whether the Ministry of Health banned the marketing of medicines based on Hydroxyquinoline in 1982 on the basis of world-wide reports of injurious effects due to the use of this drug and subsequently in 1983 issued another notification for allowing the marketing of this drug in combination with other drugs for the treatment of diarrhoea and dysentery. Knowing full well that the drug is harmful, dangerous and a large number of cases of blindness and paralysis have been detected with the consumption of this drug, how has the Ministry of Health allowed the combination of these drugs with this

drug to continue for consumption in the country, all the more so when Ciba-Geigy, a Swiss company which the originator of this drug, has withdrawn this drug throughout the world and also paid huge compensations to the people who became blind by the use of these drugs?

MR. CHAIRMAN: You will have on second supplementary if you go on.

SHRI NAND KISHORE BHATT: I would like to know from the hon. Minister why such an injurious drug whether individually or in combination with other drugs has not been banned in our country where the majority of people are ignorant about the adverse effects of medicines and also lack knowledge of adverse effects of these drugs.

SHRI S. KRISHNA KUMAR: Sir, this particular anti-diarrhoeal drug has been banned in about eight countries but is continuing to be marketed in about 34 countries including Australia, Belgium, France, Canada, Denmark, Germany and Italy.

SHRI VISHVAJIT PRITHVIJIT SINGH: No, this is wrong.

MR. CHAIRMAN: Nobody can contradict the Minister?

SHRI VISHVAJIT PRITHVIJIT SINGH: Sorry.

SHRI KRISHNA KUMAR: At no time have the Government of India banned these drugs. The query of the hon. Member is relation to the drug having been once banned and later on allowed is not factually correct.

Sir, there is a laid-down procedure under the Drugs and Cosmetics Act for banning of drugs in the country. As per this procedure, we have requested the ICMR and an expert panel in the country to give their opinion about the continuance of these drugs in India. The ICMR has

clearly said that it was not necessary to suspend the production and sale of these drugs, ICMR, of course, have made several other recommendations. On the basis of these recommendations we have made this drug a Schedule (h) drug, which is available only on the prescription of a Registered medical practitioner. We have also taken some steps to screen and stop some other combinations of the drug. It is true that some cases were reported from Japan as early as 1970 and the Government of India have, on the basis of these reports, stipulated a cautionary note in the package itself. They have also given wide publicity through the Indian Medical Association and through the manufacturers of possible side effects of the drug.

MR. CHAIRMAN: One minute only. You had taken three minutes last time.

SHRI NAND KISHORE BHATT: Swedish doctors and consumer-oriented groups such as 'social audit' boycotted the products of Ciba-Geigy, which was marketing this drug till the Company was obliged to withdraw its products based on this drug. I do not understand when the original company has already withdrawn, why should we allow use of this compound which has injurious side effects. It is a social crime. I would like to have an assurance from the Hon. Minister and protection from the Chair that use of this injurious drug is banned in our country too.

SHRI KRISHNA KUMAR: Eighteen companies are marketing this drug in this country. It is correct that one of the companies called Ciba-Geigy and its India counterparts have voluntarily withdrawn these drugs. It seems to be part of one of their global strategies. We are not bound to ask others to withdraw just because this one and some others have withdrawn it.

DR. JOSEPH LEON D'SOUZA: In 1982, the Government of India issued a notification banning the use of Hydroxyquinoline group of drugs in the country. Subsequently in 1983, another Notification was issued permitting the marketing and use of Hydroxyquinoline in combination with other drugs for the treatment of diarrhoeal disease. I would like to know from the hon. Minister, being fully conscious of the dangerous effect of the dreaded drug which has been internationally established whether any systematic clinical trials of the combination drugs marketed today in India have been conducted prior to the issuance of this subsequent notification.

If so, kindly furnish information regarding names and credentials of the investigating authorities, centres where the trials were conducted and their findings.

- If this exercise has not been done, will the hon. Minister explain why the people of India are exposed to a horrible health hazard, when the ill-effects of the drug have been proved beyond doubt. Are we wanting to enact another hidden Bhopal? This is a warning the world has given you, Please pay attention to it.

SHRI S. KRISHNA KUMAR: This particular drug has been widely used as profillactic as well as curative in the treatment of gastroenteritis disorders which are quite endemic in our country. Our investigations through the ICMR have established through their reports that no adverse side-effects of this drug have been established in any tangible manner. I have already said that more than 34 countries, including developed and undeveloped, are still using this drug. This drug is a fairly cheap drug and its alternatives which are available are more expensive and have side effects.

DR. JOSEPH LEON D'SOUZA: I have asked for an information and that has not been given.

MR. CHAIRMAN: That is all. That is the information he has. You put another question.

SHRI VISHVAJIT PRITHVIJIT SINGH: Merely giving a reply that thirty-four countries in the world are using this drug is no excuse for India to use this drug which has been proved to be harmful. The Government by its own Notification, which I would like to read out to the Minister because he said it was never banned in India, said:

"G.S.R. 578(E).—Whereas the Central Government is satisfied that the use of the drugs specified in the Table below is likely to involve risk to human-beings or the said drugs do not have the therapeutic value claimed or purported to be claimed for them....

Now, therefore, in exercise of powers conferred by Section 26A of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government hereby prohibits the manufacture and sale of the said drugs, namely:—

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#### Table

Sl. No. 13. Fixed dose combinations of Hydroxyquinoline group of drugs . . ."

This is the notification dated 23rd July, 1983 and the Honourable Minister has said just now that his Ministry has not issued a notification banning this drug. Mr. Chairman, Sir, very shortly our Government will be coming out with a new drug policy and the Ministry of Health has to be active. The Ministry of Health has to coordinate with the Ministry of Industry and with the Ministry of Chemicals which is part and parcel of this policy and ensure that this sort

of malpractices do not creep in. We have to do a review of thousands of combinations and formulations which are available in this country and many of which are totally useless ...

MR. CHAIRMAN: Time up. Put the question.

SHRI VISHVAJIT PRITHVIJIT SINGH: Only 20 seconds. I would, therefore, like an assurance but not an answer from the Honourable Minister that this sort of exercise would be done, that these drugs will be banned and the new drug policy will contain a paragraph actually specifying that a time-to-time review of drugs available in the country will be done to see which are to be withdrawn and which are to be kept.

SHRI S. KRISHNA KUMAR: Sir, there is no anomaly in the answer given by me earlier. The particular notification which the hon. Member referred to, relates to fixed dose combination of drugs having hydroxyquinoline, but they are not meant for diarrhoea. The particular question relates to the use of drug in diarrhoeal diseases.

Secondly, Sir, we do not consider this as a harmful drug, because the Ministry is guided only by the technical experts statutorily enjoined to give advice. As far as the role of the Ministry of Health in the formulation of drug policy is concerned, as the hon. Member is aware the Ministry of Chemicals is the nodal Ministry for the formulation of the drug policy. We would like to assure the hon. Member that the Ministry of Health will play its rightful role in ensuring the availability of cheap, life saving and essential drugs for the common man, assuring the quality of production and delivery of drugs in the new drug policy.

SHRI M. KADHARSHA: Sir, the goal of the Government is: "Health for all by 2000 A.D.". If the production and sale of dangerous drugs go unchecked without any effective

control by the Government it will not be "Health for all", but "death for all". Sir, the multi-nationals are dumping their drugs in the third world countries and treating the people as guinea-pigs. Sir, many drugs banned in the West are made and sold in India under some other brand names. For instance, Butazolidin is a drug which should be used only when there is no other treatment available. But in India it is administered even to young children. The Ciba Geigy has withdrawn the medicine due to world pressure after 15,000 people had died in the U.K. So, I would like to know from the Honourable Minister whether the Indian subsidiaries of the multi-nationals are making and selling the drugs under different brand names? If so, what steps the Government of India is going to take to ban this medicine?

SHRI S. KRISHNA KUMAR: Sir, the process of weeding out harmful drugs and drugs of insufficient therapeutic value is a continuous process being carried out by the Ministry of Health. I have already stated the procedure for the identification and banning of these drugs. We have already banned 22 major drug combinations, making use of the additional powers which we have armed ourselves with in 1983. The banning of drugs goes by all permutations and combinations in different countries. Sir, some countries ban some drugs and others use it. Ultimately it is a national decision depending on the disease pattern of the country, the extent of outreach work, endemic nature of the disease and the cost benefits ratio.

SHRI M. S. RAMACHANDRAN: Mr. Chairman, Sir, the hon. Minister has not explained to the earlier supplementary that they issued first notification banning the use of these drugs and subsequently modifying their earlier order. I would like to know from the Minister whether any study was conducted by any competent authority with regard to that aspect?

At least, I would like the hon'ble Minister to explain that aspect. Further, Sir, it is not a healthy convention for the Health Ministry always to justify the action taken by the bureaucrats to favour certain vested interests, who are manipulating the things and playing with the health of the people of this country. On earlier occasions also, I had put the same question. When some comments are made by the competent people about the hazardous nature and the effect of certain drugs to the health of the people, instead of their leaving the matter to ICMR or some other body and making a study, they are taking years to come to a decision. Will they take a safer path of banning the use of the drug immediately and then go on with their study?

**SHRI S. KRISHNA KUMAR:** Sir, I do not think the course of action suggested by the hon'ble Member is pragmatic. We have our own method and ICMR is one of the eminent bodies of scientists and we have laid down the procedure. If we overreact to complaints, there will be a terrible amount of destability in the whole drug dispensing picture in the country.

**SHRI M. S. RAMACHANDRAN:** Sir, he has not answered that aspect.

**MR. CHAIRMAN:** Neither you nor the Minister knows the entire thing.

**श्रीमती मैमूना सुल्तान :** सर, एक ऐसा हो गया है कि ड्रग्स के बारे में यहाँ सवाल होते हैं तो बिल्कुल उसी लाइन में जवाब उनकी तरफ से आता है। जहाँ तक कंट्राइक्शन का सवाल है वह बिल्कुल पैदा ही नहीं होता। सबमिसन हम बार-बार बार-बार करते रहते हैं। जहाँ तक बेंड-ड्रग्स का सवाल है, प्रिमीसेस और एवीडेन्स दोनों ड्रग्स में यहाँ पर आपने इजाजत दे रखा है। मैं आपसे पूछना चाहूंगी कि क्या यह सही नहीं है कि यह जो बेंड-ड्रग्स है, डब्लू० एच० ओ० की लिस्ट में, जिसको तमाम डेवलपिंग कंट्री और

अण्डर डेवलपिंग कंट्री में माना जाता है और दूसरे मुल्कों में माना जाता है, हमारे यहाँ नहीं माना जाता है? उसमें इस ड्रग को क्लिनिकलीनल जो क्लॉज है इसको बन किया गया है। आप दूसरी बाजों में डब्लू० एच० ओ० की लिस्ट को मानते हैं, इसको वाम्बोनेशन में नहीं मानते हैं, तो क्यों नहीं मानते हैं? दूसरी बात यह है कि आप यह कहते हैं कि वहाँ की क्लाइमेट-कंडीशन और है, दूसरी जगहों की जो क्लाइमेट कंडीशन है, हमारे यहाँ से डिफरेंट है, इसलिए बेंड-ड्रग्स की इजाजत देते हैं, ऐसा एवीडेन्स में आप कहते हैं? हमारे यहाँ की जो क्लाइमेट कंडीशन है, वह क्या बांगला देश में अलग है, वह क्या दूसरी कंट्रीज से अलग है? बिल्कुल नहीं है। तीसरी बात आपके पास क्या एवीडेन्स है कि आपने कोई क्लीनिकल सर्वे किया है? जो आप कहते हैं कि ऐसी कोई बात नहीं आयी तो क्या यहाँ पर वह दवा खाने से कोई ब्लाइंडनेस नहीं हुई? मैं आपको उदाहरण दे सकती हूँ... (समय की घटी) तो मैं आपसे जानना चाहूंगी कि आप इस और कब कदम उठाएंगे?

**MR. CHAIRMAN:** Mr. Minister, you will reply to whatever has been put. (Interruption). No, no. Please sit down.

**SHRI S. KRISHNA KUMAR:** Sir, as soon as a drug is banned, the W.H.O. intimates the details of the drug which is banned in any Member country. It is not recommendatory or mandatory, it is only an intimation. No country, in the world, immediately bans a drug on the basis of the W.H.O.'s information. Out of 31 names of drugs intimated by the W.H.O. as banned in other countries, in about 10 cases, we have issued the ban order. In 16 cases, the drug was not, in the first instance, being marketed in the country and there are only 7 remaining cases, where the Government of India have taken a conscious decision not to ban the drug on the basis of the expert advice made available to us.

MR. CHAIRMAN: Now, next question 142. (Interruption) No, I have given 20 minutes to this question. Therefore, next question.

**Memorial in Memory of Freedom Fighters Deported to the Andaman and Nicobar Islands.**

@\*142. DR. MOHD. HASHIM KIDWAI: Will the Minister of HUMAN RESOURCE DEVELOPMENT be pleased to state whether Government have any proposal under their consideration for setting up a suitable memorial in the memory of those freedom fighters who had been deported to the Andaman and Nicobar Islands?

THE MINISTER OF STATE IN THE DEPARTMENTS OF EDUCATION AND CULTURE (SHRIMATI SUSHILA ROHATGI): The Cellular Jail has already been set up as a national memorial, the administrative block is being maintained as a Museum, by the local administration, photographs of freedom fighters and other materials have already been exhibited in the Museum.

MR. CHAIRMAN: Dr. Hashim Kidwai. No supplementary? Mr. Ramanand Yadav.

श्री रामानन्द यादव : मान्यवर, देश के आजाद होने के तत्काल मैंने सेल्युलर जेल विजिट किया। क्या सरकार को मालूम है कि जेल के कुछ हिस्से को हॉस्पिटल के रूप में कनवर्ट कर दिया गया है? क्या सरकार इस बात पर विचार करेगी कि जो सारा पुराना जेल है उसको फ्रीडम फाइटर्स के मोन्यूमेंट के रूप में प्रिजर्व किया जाय और जिन कमरों में जो फ्रीडम फाइटर्स थे—अभी उनका नाम लिखा हुआ है छोटे अक्षरों में—वहाँ उनका नाम लिखेगी और उनकी एक शार्ट हिस्टरी लिखाने की व्यवस्था करेगी, साथ ही उसके सामने जो बड़ा सा मैदान है उस मैदान में एक मेमोरियल पिलर खड़ा करेगी, एक हाल बनायेगी जिसमें यादगार के रूप में जितने फ्रीडम फाइटर्स थे उनकी हिस्टरी रखने की व्यवस्था करेगी?

@Previously starred Question 62, transferred from the 27th February, 1986.

MR. CHAIRMAN: You must ask questions. You should not go on giving suggestions.

SHRI RAMANAND YADAV: I want an assurance.

MR. CHAIRMAN: No assurance can be asked for...

SHRI RAMANAND YADAV: We can extract an assurance from the Ministers by putting questions.

MR. CHAIRMAN: I will tell you the correct procedure. If you merely make suggestions, it will be only suggestions for action. Therefore, you must ask a question so that the Minister may reply to it pointedly. Yes, the Minister.

श्रीमती सुशीला रोहतगी : मान्यवर, माननीय सदस्य ने अपने सुझावों के साथ कुछ प्रश्न भी उठाए हैं जिनका मैं उत्तर देना चाहूंगी। इसके बारे में मुझे कहना है कि सेल्युलर जेल स्वयं इस समय एक नेशनल मोन्यूमेंट के रूप में डेडीकेट कर दिया है 1979 से, जिसका आप स्वागत करेंगे। दूसरे फ्रीडम फाइटर्स की मांग थी कि इसको मेमोरियल बनाया जाय। हमारे राष्ट्रपति महोदय ने पिछले वर्ष 23 फरवरी, 1985 को इसे नेशनल मोन्यूमेंट, मेमोरियल का रूप दिया। एक और मांग थी कि जो फ्रीडम फाइटर्स वहाँ रहे हैं, जो यातनाएं उन्होंने सही हैं उनकी मेमोरी को सेल्युलर जेल कम्पाउंड में कमेमोरिएट किया जाय, इसका प्रयास किया गया है। 7,22,840 रुपये कंस्ट्रक्शन पर खर्च किया गया है।

माननीय सदस्य स्वयं वरिष्ठ स्वतंत्रता सेनानी हैं, उन्होंने जो सुझाव दिए हैं उन पर विचार किया जायगा और यदि सम्भव हुआ तो उचित कार्यवाही की जायगी।

SHRI SUKOMAL SEN: Sir, it is good that in Port Blair, at the cellular jail some sort of a memorial has been set up by the Government. These freedom fighters who were deported to the cellular jail in Andaman