MR. CHAIRMAN: All right. Next Question. Question No. 23. Mr. Rajni Ranjan Sahu.

Import of sub-standard vaccines

*23. SHRI RAJNI RAJAN SAHU: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether it is a fact that a number of vaccines which are being imported are found to be of sub-standard quality;

(b) whether it is also a fact that samples are not being drawn from every consignment;

(c) if so, what are the reasons for the same;

(d) whether it is a fact that various vaccines available in the market are of very low potency;

(e) whether it is also a fact that these vaccines are not being stored under required conditions; and

(f) what is the number of vaccine samples that were drawn from the market for testing purposes during last two years, yearwise, and how many of them were found to be of low potency or sub-standard quality, indicating the names of such vaccines?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (KUMARI SAROJ KHAPARDE): (a) to (c) Only vaccines conforming to prescribed conditions of strength and quality are allowed to be imported. Under normal circumstances, vaccines, for which testing facilities are available, are tested when imported into the country for the first time. For subsequent consignments random sampling is done. Under exceptional circumstances, such as epidemics vaccines are released without testing.

(d) and (e) No reports have been received by the Government that various vaccines available in the market are of very potency and that they are not being stored under required conditions.

(f) Information will be collected and laid on the able of the Sabha.

SHRI RAJNI RANJAN SAHU: Sir, the question relates to the vaccines which are used for immunizing children and to prevent them from getting fatal diseases. So this is a serious matter and the Minister should reply categorically to my quetion. The reply read out just now is not only vague, but also is not in conformity with the earlier replies given in this House to Starred Question No. 219 dated the 7th May 1986, Unstarred Question No. 3004 dated 3-12-86, Starred Question No. 131 dated 3-4-86 and Unstarred Question No. 1493 dated 19th November 1986 and unstarred Question No. 4420 dated 27-3-86.

MR. CHAIRMAN: Who will remember all these questions and replied? What is the question you are putting?

SHRI RAJNI RANJAN SAHU: Sir, the above questions were put earlier. (*Interruptions*).

SHRI P. V. NARASIMHA RAO: Sir, if he sends the details, we will see whether there is any irreconciliability.

MR. CHAIRMAN: Yes, Mr. Sahu, you put your second supplementary.

SHRI RAJNI RANJAN SAHU: Sir, here is my question. You have said that you do not have such facilities. When you do not have such facilities in our country and when such vaccines are not conforming to the prescribed standards of strength and quality, why you do import such vaccines. Why should we import such vaccines? This is my first question.

SHRI P. V. NARASIMHA RAO: This question pertains to vaccines imported and whether they are tested at the time of import. The answer categorically is that in the case of the first import it is invariably tested. After that for the subsequent consignments, since the vaccine comes from reputed

firms about which we have not received a single complaint so far, only a random testing is done. This is the method. But if there is any instance where something has been found, we can always go into that.

SHRI RAJNI RANJAN SAHU: My second supplementary relates to the replies given to (d) and (e). I would like to know in regard to the vital child-immunising drug, oral polio vaccine, under Section 23(3) of the Drug Companies Act, whether samples were drawn for testing by the Drug Inspectors from 1980 to 1986, the number of samples drawn year-wise, the laboratories where tested, the results of such tests and the nature of action taken on each failed samples.

SHRI P. V. NARASIMHA RAO: That will come under (f).

MR. CHAIRMAN: Yes. Please sit down, Mr. Sahu. Now I call Mr. Yadav.

श्री जगदम्बी प्रसाद यादव: सभापति जी, जहां तक बच्चों के इम्यूनाइजेशन का सवाल है, उसके टीके का सवाल है, मंत्री जी ने सीधा सा उत्तर दे दिया कि जो इम्पोर्ट होता है उसको ऐक्जामिन कर लिया जाता है और हिन्दुस्तान की जितनी कंपनियां इंपोर्ट कर रही हैं, अगर आप छोड़ देने का विचार रखते हैं तो सारी की सारी दवाइयां वे गड़बड़ भेजेंगे, यह बात प्रमाणित है । लेकिन रेप्यूटेड कंपनी कहने से काम नहीं चलेगा । डब्लू० ऐच० ओ० ने भी जो विटामिन टेबलेट्स भेजी जाती हैं उनको बेकार पाया है और उनके बेकार बताने के बाद भी हिन्दुस्तान में वे चल रही हैं । हमारे माननीय सदस्य ने ठीक पूछा है कि आप रेंडम चैकिंग की रेगुलर व्यवस्था करेंगे जिससे कि हमारे बच्चों को ये टीके सटीक बैठें ?

श्री पी० वी० नरसिंह राव: मैंने अभी बताया है कि आज तक हमारे देश में ऐसी कोई एक भी मिसाल नहीं आई है कि रेंडम सैम्पलिंग में या टैस्ट न करने के कारण कोई कहीं पर नुकसान हुआ हो या घटिया माल या घटिया वेक्सीन आई हो ।

श्री जगदम्बी प्रसाद यादव: सवाल यह नहीं है । इंटरोवायोफार्म या इंटरोक्विनाल का मैं आपसे कहना चाहता हूं मैंने जांच करके बताने के लिए कहा विभाग से कि नुकसान हुआ है कि नहीं। खाने वाले को तो पता ही नहीं है कि उसको नुकसान हो रहा है जब तक कि आपके इंस्पेक्टर जांच नहीं करेंगे ।

श्री पी० वी० नरसिंह राव: माननीय सदस्य जो प्रश्न उठा रहे हैं वह अलग है । आप यह कहना चाहते हैं कि अगर किसी देश में किसी दवा या वेक्सीन के बारे में यह पता लगे कि उससे नुकसान होता है तो उसको हम क्यों इंपोर्ट कर रहे हैं।....

श्री जगदम्बी प्रसाद यादव: मैं इतना ही कहना चाहता हूं कि मैंने ऐक्जामिन करने के लिए कहा । लेकिन नुकसान होता जा रहा है जिसका कि खाने वाले को पता ही नहीं है । इसलिए जब तक आपके ऐक्सपर्ट जांच न करें, कैसे पता लगेगा कि वह ठीक है।

SHRI P. V. NARASIMHA RAO: He is citing instances where the vaccine has been found to be harmful in the country of manufacture. Any such cases will certainly be looked into and if it has been found harmful there, is no need for us to go on importing them. We will certainly look into that.

Dr. G. VIJAYA MOHAN REDDY: While appreciating the very good immunization programme conducted in our country, I would like the cold chain to be taken to the village; then only the programme will show good results, especially regarding polio vaccine. Very often the quality of the vaccine deteriorates. The success of the programme depends on a lot of funds being made available by the Government of India. A lot of money has to be put into this immunization

programme. Then only this programme can become a most potent weapon in combating infectious diseases.

SHRI P. V. NARASIMHA RAO: There are two directions in which we have to attack the problem. One is to strengthen the whole chain. We have decided to do that. We are doing that. And there has been a perceptible improvement from year to year. We are in this process only for two years now. As compared to the last year, there has been an improvement. We are to complete the entire coverage of the country by 1990. I am sure that the coverage as such will be completed. But I cannot say, I cannot guarantee that particularly in the case of oral polio vaccine we will be able to strengthen the whole chain to such an extent that I would say with hundred per cent confidence that there is no deterioration. That cannot be the position. That will require, as the hon. Member says, large outlays. But there is another direction in which research needs to be carried out, whether we can replace this vaccine by some other vaccine which would not deteriorate so quickly. But, again, that is a time-consuming process. I am sorry I cannot give a guarantee that at the end of 1990 there will be another vaccine which will be perfect at the other end of the delivery. Vaccines will undergo some deterioration. We will have to constantly attack the problem from different angles.

SHRI SURESH PACHOURI: Mr. Chairman, may I know from the hon. Minister what are the requirements for the import of vaccines? Secondly, what are the conditions an importer has to fulfil for obtaining import licence?

KUMARI SAROJ KHAPARDE: I would like to tell the hon. Member that there are specific rules under which the importer has to fulfil certain conditions while applying for an import licence. The importer has to file an application in Form-8 for the grant of import licence which shall be accompanied by an undertaking in Form-9, signed by or on behalf of the manufacturer. The Licensing authority shall not grant the licence unless he is satisfied that the premises where imported drugs will be stocked by the importer are provided with proper accommodation for preserving the properties of drugs, to which the licence applies. The second part is very long. If the hon. Member is really serious, I can write to him or give ...

MR. CHAIRMAN: You can send a letter to him. Shrimati Chowdhury.

SHRIMATI RENUKA CHOWDHURY: Sir, I would like the hon. Minister to clarify one point in the event of taking into consideration all the inherited limitations we have regarding vaccines and the potency and deterioration, etc. There have been failures, we know. Andhra Pradesh was one of the victims of failure of potency in polio vaccine where there was an epidemic breakout. Now, has the Ministry taken into consideration the prophylatic steps that it will take to prevent the spreading of epidemic outbreaks in the event of vaccines breaking down? This means also putting up notices in airports, railway stations, etc. and prohibiting children of certain parts from travelling from State to State, for preventing the epidemic. We have had people travelling on aircrafts with chicken pox and measles, which were communicated to other passengers 20 days after the event, because the aircraft is practically, virtually an incubating...

DR. BAPU KALDATE: That is why the doors are open in it. Don't worry. (*Interruptions*)

SHRI P. V. NARASIMHA RAO: Dr. Bapu Kaldate has given a very fitting reply. Sir, the point is that the whole programme is prophylactic. But it is being undertaken in phases. After 1990, we are sure, this question will not arise because by that time the whole country will be covered.

श्री मीर्जा इर्शादबेग : मान्यवर, मैं मंत्री महोदय से जानना चाहूंगा जैसा कि बताया गया कि पोलियो वैक्सीन को जीरो डिग्री पर रखा जाना चाहिए जिसकी वजह से इसका अफेक्टिवनैस ज्यादा हो, ऐसे कई केसेज भी पाये गये हैं जिसमें देखा गया कि उन्होंने अपना अफेक्ट गवां दिया है तो वर्तमान संजोगों के संदर्भ में हमारे देश में वर्तमान क्या व्यवस्था है या कितनी लेबरोट्री जिनसे हम जानकारी ले सकते हैं ये जो वैक्सीन हैं ये अफेक्टिव हैं या नहीं और आगामी दिवसों के लिए इस व्यवस्था की सुधार के लिए हमारा क्या आयोजन है ?

श्री पी० वी० नरसिंह राव : मैंने अभी निवेदन किया है कि यह जो कोल्ड चेन व्यवस्था है उसको बहुत ज्यादा हमें पक्का बनाना पड़ेगा और हम देख रहे हैं कि थोड़ा बहुत, वेक्सीन असर कम हो जाता है । इसका अर्थ यह नहीं है कि वह बिल्कुल पानी-पानी हो जाता है, उसका कोई असर रहता ही नहीं । जो असर हम चाहते हैं, वह नहीं होता है क्योंकि जहां कोल्ड चेन ठीक नहीं होता, उसका टैम्परेचर जो भी होना चाहिए उससे जरा बढ़ जाता है और उसका असर कम हो जाता है । मैं समझता हूं यह नहीं कहा जा सकता निश्चित तौर पर कि किस गांव में पहुंचते वक्त कौन सा कन्साइनमेंट, किस दिन, क्या हुआ । आमतौर पर देखा जाता है कि उस इलाके में पहुंचने में इतनी देर हो जाती है कि टेम्परेचर बढ़ जाता है और उसका असर कम होने की आशंका है तो फिर उस इलाके में कोल्ड चेन का स्ट्रैंथन करने के बारे में कोई खास उपाय किया जाता है । एक-एक गांव के बारे में एक-एक स्थल के बारे में यह नहीं किया जा सकता । इट इज जस्ट नॉट पासिबल प्रेक्टीकली ।

DR. (SHRIMATI) NAJMA HEPTULLA: Sir, the hon. Minister has given the reply in great detail. He has stated in his answer that these vaccines are all protein based and that is why it is required that they should be kept at a certain temperature. While replying, the hon. Minister has stated that there is going to be research in order to find out some vaccine which can be stored at higher temperature. I would like to know whether there are any efforts being made for such R. & D. in our country or whether we are waiting for other countries to do the research.

SHRI P. V. NARASIMHA RAO: Research is something which every country does to the extent it can. It is not necessary to wait for the other countries to do it. Nor does any country ask the other countries to wait until it does it. It is continuously going on in all countries. Some country may stumble into a solution earlier than the others. In regard to vaccines which can remain effective at higher temperature, I am afraid I cannot give any time limit. I am sure that there will be break-through in course of time. I cannot say when.

Observation of International Women's Day

*24. SHRIMATI SUDHA VIJAY JOSHI:†
SHRI KALPNATH RAI:

Will the Minister of HUMAN RESOURCE DEVELOPMENT be pleased to state;

(a) whether International Women's Day was observed in India on March 8, 1987;

†The question was actually asked on the floor of the House by Shrimati Sudha Vijya Joshi.