RAJYA SABHA

Friday, the 11*th March,* 2005/20 *Phalguna,* 1926 *(Saka)*

The House met at eleven of the clock,

MR. DEPUTY CHAIRMAN in the Chair.

REFERENCE BY THE CHAIR

75TH ANNIVERSARY OF DANDI MARCH

MR. DEPUTY CHAIRMAN: As the hon. Members are aware, on the 12th March, 2005, the nation celebrates the 75th Anniversary of the Dandi March. On this historic occasion, the Father of the Nation, Mahatma Gandhi, along with several patriotic volunteers, challenged the imposition of Salt Tax by the British Government. The non-violent protest through the medium of Salt Satyagraha had an appeal across regional, class and ethnic boundaries throughout the country.

On this occasion, we pay homage to the memory of the Father of the Nation and the non-violent Satyagrahis whose heroic efforts contributed towards the independence of the country.

ORAL ANSWERS TO QUESTIONS

Banned medicines

*141. SHRI SHAHID SIDDIQUI: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether Government are aware of the fact that many medicines, used in India, are banned abroad for a long time;

(b) if so, the details of those medicines alongwith their names; and

(c) whether Government have taken any action to ban them in India; if so, the details thereof and if not, the reasons therefor?

THE MINISTER OF HEALTH AND FAMILY WELFARE (DR. ANBUMANI RAMDOSS): (a) to (c) A Statement is laid on the Table of the House.

Statement

There is no system of global banning of drugs. Certain drugs and formulations withdrawn in one or more countries may continue to be marketed in other countries. The decision to ban a drug by the regulatory authorities is normally based on the risk assessment process which is influenced by a number of factors such as disease pattern in a country, indications and dosages of the drug permitted, varying reactions of certain ethnic groups in a given population, availability of safer substitutes and overall safety profile of the drug. It is a well-known fact that administration of any drug is not absolutely free from side effects or adverse reactions in a statistically insignificant minority of the population.

There is an adequate mechanism in India to review the status of the drug formulation as and when any serious adverse event is reported in the International journals, WHO Newsletters or when a drug formulation is reported to have been withdrawn in some countries. The use of the drug, so reported, is assessed in consultation with the experts, based on available technical information, benefit-risk ratio, local needs etc. The matter is further considered by the Drugs Technical Advisory Board (DTAB), a statutory body under the Drugs & Cosmetics Act, 1940.

Seventy six categories of drug formulations have so far been prohibited in the country by the Central Government, which were considered irrational or harmful in the context of present knowledge. In the recent past, drugs like Astemizole, Terfinadine and Rofecoxib have been prohibited after due assessment of their benefit-risk ratio by the experts, while drugs like Analgin, Hydroxyquinoline, Furazolidone, Phenylpropanolamine, Nimesulide etc. have been permitted to be continued to be marketed after due examination of their safety and use in the country.

A National Pharmacovigilance Programme has been launched in 2004 to capture data on adverse reactions to drug use in the country.

†**श्री शाहिद सिद्दिकी:** सर, आज जो मेडिसिंस बाजार में आ रही हैं, इनमें बहुत बड़ी तादाद में नकली दवाएं बन कर आ रही हैं। उसे रोकने में अभी तक सरकार कामयाब नहीं हुई है। जो भी कदम उठाए गए हैं, उनके खातिरख्वाह नतीजे नहीं निकले हैं। क्या इसमें सरकार इस तरह के कदम उठाएगी, जिससे इसे रोका जा सके और इसमें सख्त-से-सख्त सजा दी जा सके? क्या इसके लिए कानून में कोई तब्दीली की जाएगी?

†Translation of Urdu Script.

شری شاہد صدیقی : سر، آج جو میڈیسن بازار میں آ رہی ہیں، ان میں بہت بڑی تعداد میں نقلی دوائیں بن کر آ رہی ہیں۔ اسے روکنے میں ابھی تک سرکار کامیاب نہیں ہوئی ہے۔ جو بھی قدم اٹھائے گئے ہیں، اس کے خاطر خواہ نتیجے نہیں نکلے ہیں۔ کیا اس میں سرکار اس طرح سے قدم اٹھائے گی، جس سے اسے روکا جا سکے اور اس میں سخت سے سخت سزا دی جا سکے؟ کیا اس کے لئے قانون میں کوئی تبدیلی کی جائے گی؟

DR. ANBUMANI RAMDOSS: Sir, I understand the concern of the hon. Member about the spurious drugs in the country. There are some issues pertaining to different parts of the country where spurious drugs are being sold. The Government of India is committed to taking stringent steps to curb this malpractice. We are also trying to bring in stringent provisions through legislation. In fact, we are trying to bring some of the changes required to be made to some of the provisions, as recommended by the Mashelkar Committee, before this august House for enactment to make this offence cognisable and to increase penalty, etc. This was placed before the Cabinet and the Cabinet wanted some modifications. After modifications and the Cabinet's approval, this would be brought before the House.

We have the Central Drug Controlling Authority and the State Drug Controlling Authorities. We also have the Central and the state Drug Inspectors.

Currently, the Indian pharmaceutical industry is the fourth biggest in the world and is growing at a very rapid pace. Currently, the regulatory mechanism is lagging a little behind. Therefore, the Government is trying to prune-up this mechanism. We are trying to go in for capacity-building process whereby we are modernising all drugs and food labs all over the country and sensitising all our offices—at the Central and at the States-level—and imparting them training and asking them to go and check spurious drugs. This is a very issue and we are looking at it.

†**श्री शाहिद सिद्दिकी:** सर, इसमें सरकार के बनने के बाद आपने जो स्टेप्स लिए हैं, वे काबिले तारीफ हैं, लेकिन एक तो दवाओं के दाम का मसला है .....दाम के मामले में बहुत ज्यादा प्रोफिट लिया जाता है। जो दवा 10 पैसे, 20 पैसे की बनती है, वह बाजार में 10 रुपए, 20 रुपए में बिकती है जिसे कारण आम आदमी तक मेडिसिन की पहुंच नहीं हो पाती। महोदय, इसकी एक वजह यह भी है कि नकली दवाओं के दाम और प्रोडक्सन कॉस्ट में बहुत बड़ा फर्क है व मुनाफा बहुत ज्यादा है। जब तक हम इस फर्क को नहीं हटाएंगे तब तक spurious दवाएं बननी बंद नहीं होंगी। इसलिए spurious दवाओं के बनने को रोकने के लिए price mechanism को देखना बहुत जरूरी है। आप इस बारे में क्या कार्यवाही कर रहे हैं?

†Transliteration of Urdu Script.

شری شاہد صدیقی : سر، اس میں سرکار کے بننے کے بعد آپ نے جو اسٹیپس لئے ہیں، وہ قابل تعریف ہیں لیکن ایک تو دواؤں کے دام کا مسئلہ ہے۔ دام کے معاملہ میں بہت زیادہ پروفٹ لیا جاتا ہے۔ جو دوا دس پیسے، بیس پیسے کی بنتی ہے وہ بازار میں دس روپے، بیس روپے میں بکتی ہے۔ جس کی وجہ سے عام آدمی تک میڈیسن کی پہنچ نہیں ہو پاتی۔ مہودے، اس کی ایک وجہ یہ بھی ہے کہ نقلی دواؤں کے دام اور پروڈکشن قیمت میں بہت بڑا فرق ہے اور منافع بہت زیادہ ہے۔ جب تک ہم اس فرق کو نہیں ہٹائیں گے تب تک spurious دوائیں بننی بند نہیں ہونگی۔ اس لئے spurious دواؤں کے بننے کو روکنے کے لئے پرائز میکانزم کو دیکھنا بہت ضروری ہے۔ آپ اس بارے میں کیا کارروائی کر رہے ہیں؟

MR. DEPUTY CHAIRMAN: Mr. Shahid Siddiqui, I think, the issue of price mechanism does not come under this Ministry.

DR. ANBUMANI RAMDOSS: Yes, Sir.

†श्री शाहिद सिद्दिकी: सर, spurious medicines से इसका ताल्लुक है ...(व्यवधान)...

شری شاہد صدیقی : سر، spurious میڈیسن سے اس کا تعلق ہے.....مداخلت.....

MR. DEPUTY CHAIRMAN: You can put this question to the concerned Ministry. The price mechanism issue is looked after by some other Ministry.

DR. ANBUMANI RAMDOSS: Sir, my Ministry is concerned with the quality and standard of drugs, whereas price mechanism is dealt with by my hon. friend Shri Paswanji who is taking a lot of steps ...(*Interruptions*)..

†श्री शाहिद सिद्दिकी: सर, प्राइस मैकेनिज्म, spurious medicines के साथ जुड़ा हुआ है। इसमें प्रोफिट बहुत ज्यादा है, इसलिए नकली दवाएं बनती हैं। ...(व्यवधान)... प्रोफिट सौ गुना है, इसलिए नकली दवाएं बनती हैं।

شری شاہد صدیقی : سر، پرائز میکانزم، spurious میڈیسن کے ساتھ جڑا ہوا ہے۔ اس میں پرافٹ بہت زیادہ ہے اس لئے نقلی دوائیں بنتی ہیں۔.....مداخلت..... پرافٹ ۱۰۰ گنا ہے، اس لئے نقلی دوائیں بنتی ہیں۔

DR. ANBUMANI RAMDOSS: Sir, my hon. colleague, Shri Paswanji, is taking a lot of steps to control the prices for the benefit of the people.

†Transliteration of Urdu Script.

SHRIMATI VANGA GEETHA: Mr. Deputy Chairman, Sir, I would like to know from the hon. Minister about the standards of drug research in India. And, if they are not of international standard, what are the steps contemplated by the Government of India for strengthening drug research in India so that they could be on a par with the international standards? Has any research or investigation been initiated for drugs which are banned abroad, but are available in the Indian market and are being used by our countrymen?

DR. ANBUMANI RAMDOSS: Sir, Indian R & D industry is growing at a rapid pace and competing with the world market. We could proudly say that the Indian R&D today is one of the bests in the world. And, equally, the Government is trying to regulate it so that more ethical issues and ethical standards could be put into research. And, it is not that people who come to India do research and after clinical trials get away. We have our own National Ethical Council through the ICMR, we have our own State regulatory bodies, we have the National Pharmaco Vigilance Committee which has been constituted recently to curb these practices or malpractices in drugs and research.

Coming to the second part of the question which relates to the drugs which are banned in other countries, but are being used in our country, I would like to say, Sir, that no drug is globally banned. And there is no organisation which can ban a drug globally. Decisions with regard to banning of drugs are taken at the highest level in each and every country, where it is marketed or manufactured. Like, if a drug is banned by the FDA in America, it is not automatically banned in other countries. There are different issues like drugs could be metabolised differently between different individuals and between different ethnic groups. For example, Sir, drug 'A' could be metabolised very quickly in Shri Jairam Ramesh. ...(*Interruptions*).. The same drug could be metabolised very slowly in Mr. Narayanasamy, although both have the same body mass. In Indian people, drugs can be metabolised very fast. The same drug could be metabolised very slowly in white people. So there are different issues. It is not like automatic banning. In India, we have our own experts, we have our own Drug Technical Advisory Board, National Pharmaco Vigilance Committee, to look into each and every issue of drugs being banned and according to merits we go about it.

SHRI SANTOSH BAGRODIA: Sir, the pharmaceutical companies all over the world, which have been going to China, are willing to come to India. The cost of production in India is one-tenth of the cost they are spending there. I would like to know from the hon. Minister whether he has any plan, particularly with regard to Intellectual Property Rights, which

have also been legislated now, so that they can be invited with better policies. They are all willing to come over here. It is only a question of making more efforts so that exports from here can also increase. My second point is, cyclosporin is something which is required by every individual whoever gets a transplant. Sir, I can tell you there are hundreds and thousands of cases in the country where poor patients get the treatment by NGOs etc. But, the moment he comes out of hospital, he cannot afford cyclosporin which is required for the whole life. As a result, a number of NGOs have stopped giving help to these poor patients by saying, 'if they cannot afford later on, what is the use?' So, what effort is the Government of India making on a medicine like this so that it becomes affordable for the poorest patient in the country?

DR. ANBUMANI RAMDOSS: Sir, anybody is welcome to India to manufacture drugs provided they follow legislative, ethical and other legal issues involved. As I said, the Indian pharmaceutical industry is the fourth largest industry in the world. Ours is the second highest FDI-approved industry in the world, after the USA. That is how the Indian pharmaceutical industry is going about now.

Coming to the second issue of use of cyclosporin after kidney transplant, we found that it is quite expensive and the patients could not afford to buy. Under the National Illness Assistance Fund we supply this to some of the patients. But to bring down the prices of cyclosporin, I would say that I have to look into the issue.

SHRI MANOJ BHATTACHARYA: Sir, you were the chemical and fertilizers Minister earlier. So, you are very much aware about this. The hon. Member has raised an issue with regard to prices of medicines. That is a different subject and other Ministry — not Health — is responsible for it. And, Mr. Paswan, I understand, is trying to do an excellent job in this regard. I do not know how far he could advance till now. I wish him all the best.

Sir, the hon. Health Minister himself is a medical practitioner. I would like to know whether some of the Fixed Dose Combinations have been found to be irrational. You have banned 76 FDCs. But, some of the drugs, for example, Cisapride allowed to be sold only on the prescription of a Gastroentologist having a DM Degree. Now, would the hon. Minister tell us whether there is any regulatory mechanism to see that the prescription has been written by a Gastroentologist with DM or something more than that. That is number one.

MR. DEPUTY CHAIRMAN: You put your question. There are many Members who wish to put supplementaries.

SHRI MANOJ BHATTACHARYA: The second one is this. There are some aphrodisiac drugs like Sildenafilcitrate. What do you do? You have recommended that only urologists or the specialists should prescribe. But, Sir, they are being openly sold in the market. So, irrational drugs are available aplenty in the market and the Government does not have any regulatory mechanism to the extent required. At the same time, the moral and ethical values — I am not going to comment about that — are coming down. In fact, we wanted some discussion on this.

MR. DEPUTY CHAIRMAN: You put your question.

SHRI MANOJ BHATTACHARYA: These are the questions. What the Government is doing with regard to combinations, FDCs, like Nimesulide and Paracetamol? They are banned everywhere. There are many other FDCs, particularly tonics, containing horrible and most irrational things which have been banned even in Bangladesh but the Government of India could not ban them here.

DR. ANBUMANI RAMDOSS: Sit, till date, 76 FDCs, some combinations and some individual drugs are banned in India. My hon. friend has brought out some issues. But, there are also some issues in Kerala. There is a drug called Latrozole. The Drug Controlling Authority prevented doctors from prescribing this drug.

SHRI MANOJ BHATTACHARYA: Mine is a different question.

DR. ANBUMANI RAMDOSS: I know that. The drug is different but the issue is same. The Authority said that only a specialist should prescribe it. We are looking into this. As such, there is no legislation today to say that only a specialist should prescribe it. The Government is seized of this issue. We will look into it.

SHRIMATI N.P. DURGA: Sir, in our country we have only 515 drug formulations which are sold with 3000 different names. These medicines are banned in other countries and the production and sale of those is crime. These medicines are dangerous and can produce paralysis, cancer, blindness, and produce many other dangerous sickness and makes the immune system of the man weak and the person can die. Sir, I have a list of some of the medicines which are banned in other countries. I wish to place it on the Table of House, if the House permits.

MR. DEPUTY CHAIRMAN: You can send it to the Minister.

SHRIMATI N.P. DURGA: Okay; Sir. Now, will the Minister give an assurance that he would take an action in banning these medicines?

DR. ANBUMANI RAMDOSS: Sir, I have already answered this question that if a drug is banned outside the country, it is not automatically banned here. We have our own specialist who is going into these issues, and my colleague could also bring out this issue if there are some medicines which are banned. We could then look at it and take a decision.

SHRI JAIRAM RAMESH: Sir, I had raised my hand before the hon. Minister drew reference to my metabolic powers. Sir, this question is put to every Minister and the answer is identical. Drug quality, drug testing, drug quality control is the responsibility of the States and the Central Government can't do much about it. I would like to put before the Minister a very straightforward question. What is the road map for bringing a Central legislation in this area? This is my first question. My second question is, all the countries of the world have strong national authorities for drug testing, drug quality control, drug standards like the FDA. Is there any intention on the part of the Government to set up a strong FDA type of organisation in this country as well?

DR. ANBUMANI RAMDOSS: Sir, I would like to thank Mr. Jairam Ramesh for putting up this very valid question. The Central Government is not shying away from its responsibilities of looking into the aspects of curbing this practice of spurious drugs. In fact, the Central Government is now actively involved in this process, including the time from my predecessor. She was very actively involved in curbing this practice of spurious drugs. She had taken a lot of steps in this regard, and I am also continuing with those efforts. And, we are taking several steps like the implementation of the recommendations of the Mashelkar Committee, which will go a long way in curbing these practices. Now, the Government is spending about Rs. 110 crores for capacity building and for modernisation of all the labs, both the food and drug labs — for food Lab the allocation is about Rs. 236 crores and for the Drug Lab it is Rs. 110 crores. Sir, in 1975, there was a recommendation of Haathi Committee for forming a National Drug Advisory Board; it was called the National Drug Agency. And, there were further recommendations on that in 1982. So, the Government now is thinking in terms of an independent drug authority. There are a lot of practicalities involved in this issue because the State Government is the enactment authority and the Central Government makes the policy. Like Mr. Jairam Ramesh has said, we don't shy away from that. We are also equally responsible for that. We

are looking into the issue.

*142. [The questioner (Shri C. Ramachandraiah) was absent. For answer *vide* page 29. *infra*.]

Pollution by Cement Plants in Gujarat

†*143. DR. A.K. PATEL:
PROF. ALKA BALRAM KSHATRIYA:

Will the Minister of ENVIRONMENT AND FORESTS be pleased to state:

(a) whether Cement Plants are polluting the environment of Gujarat by being set up in the residential areas of the nearby villages;

(b) whether due to this, the crops of the poor farmers are falling and roads and water facilities are being affected because of the heavy load;

(c) the reasons why they should not be shifted to anywhere in a remote area; and

(d) the rules and regulations which govern Cement Industries in this regard?

THE MINISTER OF ENVIRONMENT AND FORESTS (SHRI A. RAJA): (a) to (d) A Statement is laid on the Table of the House.

Statement

(a) There are 11 Cement Plants operating in Gujarat with valid consent of Gujarat State Pollution Control Board. The Board is regularly monitoring compliance with the consent conditions. There are no reports of specific complaints regarding violation of emission standards by these plants.

(b) There are no reports of any adverse impact on crop production and other facilities.

(c) Does not arise.

(d) Emission standards for cement industry are notified under the Environment (Protection) Act, 1986.

DR. A.K. PATEL: Sir, in Gujarat, about eleven industries are already closed because of pollution and other causes. Eleven cement units are working. These cement factories are causing pollution in the surrounding areas and we get a lot of complaints from the villagers. I would like to know the number of cases registered against the industrial units causing

†The question was actually asked on the floor of the House by Dr. A.K. Patel.