RAJYA SABHA

Friday, the 7th August, 2009/16 *Sravana,* 1931 *(Saka)*

The House met at eleven of the clock,
MR. CHAIRMAN in the Chair.

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MEMBERS SWORN

Shri Kishore Kumar Mohanty (Orissa)

Shri Parvez Hashmi (NCT of Delhi)

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ORAL ANSWERS TO QUESTIONS

Failure to check spurious drugs

*481. DR. JANARDHAN WAGHMARE:††
SHRI N.K. SINGH:

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

(a) whether Government is aware of circulation of fake and spurious drugs in Indian markets;

(b) if so, the facts and details thereof;

(c) whether various Central as well as State agencies have completely failed to put a check on the circulation of fake and spurious drugs in the country; and

(d) if so, the reasons therefor and steps Government proposes to take to ensure that fake drugs are not available in the markets?

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI GHULAM NABI AZAD): (a) to (d) A statement is laid on the Table of the House.

Statement

(a) and (b) The manufacture and sale of spurious drugs is a clandestine activity indulged in by antisocial elements which exploit the confidence enjoyed by certain fast selling drug products. The drug samples tested all over the country, however, reveal that approximately 0.3% to 0.4% of around 40,000 samples tested per annum were found spurious.

(c) and (d) No. The cases of spurious drugs are detected from time to time by the State Licensing Authorities. Recently, a spurious drug racket was busted in Gurgaon, Haryana,

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††The question was actually asked on the floor of the House by Dr. Janardhan Waghmare.

wherein stocks of finished goods, semi-finished goods, packed tablets, printed packing material, dies and punches used in the manufacturer of counterfeit drugs were seized by a team comprising of the State Crime Branch and Drug Controller Organization of Haryana. The Managing Director of the firm was arrested. In another case of import of bulk drugs from unregistered sources originating from China were also detected at Chennai sea port by the officers of Central Drugs Standard Control Organization (CDSCO). The consignments were not permitted to be released and the Customs authorities' were requested for **Absolute Confiscation and Prosecution** in these cases.

To assess the extent of spurious drugs in the country, a country wide Survey has been undertaken by the Ministry of Health, through CDSCO, on the basis of statistical principles provided by Indian Statistical Institute (ISI), Hyderabad. Under this survey, around 24,300 samples of 61 brands of drugs belonging to 9 therapeutic categories of 30 manufactures from 100 different Pharmacy outlets located in each stratum *viz.* Metros, big cities, districts, towns and villages in different regions of the country have been collected. This would help in identifying geographical areas where spurious drugs are available so that a focused monitoring is done by the concerned authorities in these areas for eliminating the menace of spurious drugs.

Other measures taken to check the menace of spurious drugs are as follows:-

1. The Drugs and Cosmetics (Amendment) Act, 2008, has been notified on 5th December, 2008, providing for stringent penalties for offences relating to spurious and sub-standard drugs and making offences under the Drugs and Cosmetics Act cognizable and non-bailable.

2. In the 39th meeting of Drugs Consultative Committee (DCC), a statutory body of drug regulators of all States/UTs constituted under the Drugs and Cosmetics Act, 1940, held on 10th December, 2008, the States were requested to play pro-active role in assessing the extent of spurious drugs in the country.

3. In the 40th meeting of DCC held on 29.6.2009, guidelines for taking action on samples of drugs declared spurious or not of standard quality in the light of enhanced penalties under the Drugs and Cosmetics (Amendment) Act, 2008, were adopted for the purpose of uniform implementation of the Drugs and Cosmetics Act in the country. The guidelines have also been placed on the web site of CDSCO.

4. Testing facilities at Central and State laboratories have been upgraded and new drug testing laboratories have also been established so as to enhance the capacity of the laboratories to test large number of samples. Under a Capacity Building Project, 23 States and 6 Central Drug laboratories have been strengthened through renovations, extensions and provided with state of art equipments.

5. Schedule M to the Drugs and Cosmetics Rules, 1945, pertaining to Good Manufacturing Practices was amended in 2001 to make it mandatory, and at par with the international standards, for the manufacturers of drugs to comply with the requirements of this Schedule for quality control of the drugs manufactured by them. The amended Schedule M was made applicable to existing manufacturers from 1st July 2005.

6. Specific training programme for regulatory officials of State Governments on logistics of intelligence work, prosecutions, etc. has been conducted.

7. Pharma industry and trade have been requested to fight the menace of spurious drugs as a shared responsibility. This would help in successfully detecting the cases of spurious drugs by regulatory authorities.

8. A meeting with representative of Directorate of Revenue Intelligence, Commissioner Customs and all port officers has been held to deliberate on modalities for absolute confiscation and prosecutions in cases of import of spurious drugs.

9. Pharmaceutical Zones, dedicated areas for handling import and export of drugs, are being developed at Port offices.

10. A whistle blower policy is being formulated whereby rewards would be given to the informers for providing information on clandestine activities relating to manufacture and trade of spurious/fake drugs.

DR. JANARDHAN WAGHMARE: Sir, the Indian market is flooded with fake and spurious drugs and medicines. These drugs come especially from China. China is also misusing our name; it is selling medicines with the label 'Made in India' in Africa. But here, Government has rather failed in prosecuting the people who are involved in this. There are rackets and especially, costly drugs and medicines are fake drugs. There must be some nexus between the officials, the manufacturers, the agents, etc., but the Government has not yet detected it.

MR. CHAIRMAN: What is the question?

DR. JANARDHAN WAGHMARE: What has the Government done in this regard? That is my question.

SHRI GHULAM NABI AZAD: Sir, it is true that insofar as spurious or counterfeit drugs are concerned, their number has increased globally and so has their number increased in our country. There has been, in the past few years, a boom in the Indian pharmaceutical industry. With that boom, there has also been an increase, or, I would rather say, temptation, on the part of some unscrupulous and anti-social elements to make quick money by floating spurious drugs. This is in the domestic market, but even internationally — I would agree with the hon. Member — very recently, it has come to the knowledge of the Government of India that some consignments of fake drugs bearing the label, 'Made in India' were seized by Nigerian authorities. The Government of India took up this matter with the Nigerian authorities and further

proved that these fake consignments had not originated from India. Rather these fake spurious drugs had originated, or had their origin, from China. In another similar case, an import of bulk drugs from unregistered sources originating from China was also detected at Chennai's sea port by the officers of Central Drugs Standard Control Organisation and the consignments were not permitted to be released. So, these consignments, with the help of Custom authorities, have been confiscated and are in their possession. Seeing the severity and magnitude of the case, we have recommended this case to the CBI to probe into.

DR. JANARDHAN WAGHMARE: Sir, apart from the Ministry of Health, the Ministry of Commerce, the Ministry of Chemicals, and even the Ministry of Finance are involved in this. But, it seems that there is no co-ordination among them. The inter-Ministerial meetings should take place and they should think over these problems very seriously. I would like to ask hon. Minister, through you, Sir, that how many such inter-Ministerial meetings have taken place during the last five years.

SHRI GHULAM NABI AZAD: Sir, hon. Member has mentioned about the co-ordination among the Ministry of Health, the Ministry of Commerce and the Ministry of Finance. Rather I would add one more Ministry, that is, the Ministry of External Affairs because once we are talking about counterfeit of medicines across the globe, then, input or the help or assistance of the Ministry of External Affairs is equally important. I would like to inform the House, through you, Mr. Chairman, Sir, that there is a perfect co-ordination among the Ministry of Health, the Ministry of External Affairs, the Ministry of Commerce and the Ministry of Finance. As a matter of fact, the second part of the question is directly related with part (a) of the question raised by hon. Member that in the Ministry of Commerce, we have an autonomous organisation called Pharmexcil which promotes the export of Indian pharma products abroad and this organisation works in close co-ordination with the Drugs Controller General of India. As a matter of fact, this Nigerian case, which had come to the notice of the Government of India, it was the Ministry of Commerce which took it up with the Chinese Government and subsequently, it was also the Ministry of External Affairs which took it up with the Government of China, and it is at their initiative that the Chinese Government, ultimately, agreed that the consignment had actually originated from China to Nigeria, not from India. Very recently, we had, at the initiative of Pharmexcil, as I have said that it is an autonomous organisation of the Ministry of Commerce, organised one function in South Africa where the Drugs Controller General of the Ministry of Health and MEA officers were present. They together discussed this issue of spurious drugs. So, we have a perfect co-ordination in so far as the Ministries are concerned. Well, I am afraid, I won't be able to say, at this moment, whether there has been, in the past, any inter-Ministerial

meeting, but keeping in view the severity and importance of the situation, I personally feel that there should be inter-Ministerial meetings.

SHRI N.K. SINGH: Considering that the Minister has recognised that there is both an external and an internal dimension of this issue, on the external side, I would be contemplating a much better sharing of intelligence information between our intelligence organisations, particularly revenue intelligence with other international intelligence organisations like INTERPOL. On the internal side, I would be contemplating the constitution of a Central drug authority pending for long incentivising whistleblowers and generally ensuring that the corporates invest much more on better packaging and labelling to prevent spurious drugs.

SHRI GHULAM NABI AZAD: Sir, for the first part, I would like to say, yes, it has ramifications not only at the national level but also at the international level. We may not have taken the assistance of Interpol so far but, as I said earlier, there is coordination between the Ministry of External Affairs and the Ministry of Commerce, which have their offices across the globe, in most of the countries; at least, the MEA has its presence across the world. For example, in the case of Nigeria and China, we have taken the assistance of these two Ministries. So, these two Ministries are always there to help us across the globe. I totally agree with the hon. Member that we need to strengthen our intelligence abroad. But, I think, we also need to strengthen our intelligence within the country, and, we have taken and we are going to take a number of initiatives.

Mr. Chairman, Sir, Dr. Mashelkar Committee, which was constituted in 2003, has given its report, and, some parts of the report, through an amendment, are going to be become law. This amendment, which is going to be a part of the Act, has been notified by the Ministry of Law in the month of December last year but it would not become law unless the Ministry of Health notifies it.

The moment Ministry of Law notified it, there was a lot of hue and cry made by the pharma industry because stringent actions are being taken under this, which includes life imprisonment. Short of capital punishment, everything is being suggested in it, and, even setting up of special courts has been suggested in the amendment. But, as I said, it could not be notified by the Ministry because the pharma industry was against it. In these past six months, the Ministry has held series of meetings with the representatives of the pharma industry, and, now we have come to the conclusion that we shall go ahead with this. Only yesterday, I have signed the papers for notification, and, within a week's time, it is going to be notified and implemented.

Sir, the Central Drug Authority is the second part of the recommendation. Subsequently, we have made all the Cabinet papers. Some more consultation is required with the State Governments, and, in the meantime, that shall also come into being.

डा0 ज्ञान प्रकाश पिलानिया : धन्यवाद, सभापति महोदय। देर आयद दुरुस्त आयद । जैसा माननीय मंत्री जी ने फरमाया है, अगर वास्तव में यह अमेंडमेंट आ जाए, जो डा0 माशेल्कर की कमेटी ने रिकमेंड किया था, तो शायद इन मौत के सौदागरों पर कुछ लगाम लग सके, लेकिन अब तक तो ज्यों-ज्यों दवा की, मर्ज बढ़ता गया। मेरा specific सवाल है कि पिछले तीन सालों में spurious drugs की manufacturing और sale करने वाले जो लोग हैं, उनके खिलाफ कितने एफआईआर दर्ज हुए और कितने लोगों को कैद की सजा मिली।

श्री गुलाम नबी आज़ाद : सर, कैद की सजा तो अब होगी। जैसा मैंने अर्ज किया कि आज लॉ नोटिफाई होगा और हफ्ते तक इसकी नोटिफिकेशन निकलेगी - कल ही हमने पेपर्स साइन किए हैं - और उसके बाद कानूनी जकड़ में ये लोग आ जाएंगे। अभी तक जो कानून था, वह इतना नरम था कि अगर कोई व्यक्ति पकड़ा भी जाता था तो उसी वक्त छोड़ दिया जाता था, ऐक्शन नहीं होता था। लेकिन अब यह नया कानून जो एक हफ्ते के बाद लागू हो जाएगा, उसके बाद जेल भी होगी, उम्र कैद भी होगी और स्पेशल कोर्ट्स बनेंगे, ट्रॉयल कोर्ट्स बनेंगे, ताकि तुरन्त स्पेशल कोर्ट के द्वारा फैसला सुनाया जाएगा। यह आने वाले वक्त में होगा।

श्री ईश्वर सिंह : महोदय, मैं आपके माध्यम से माननीय मंत्री महोदय से पूछना चाहता हूं कि भारत देश आयुर्वेदिक दवाइयों के प्रयोग में प्रख्यात है। परन्तु आयुर्वेदिक डॉक्टर्स अंग्रेजी दवाइयों का मिश्रण करके इलाज करते हैं। यह सब को पता है। आयुर्वेदिक दवाई...(**व्यवधान**)... सर, आयुर्वेदिक दवाइयों के अंदर अंग्रेजी दवाइयों का मिलाया जाना, यह भी एक मिलावट है।...(**व्यवधान**)... सर, आपने मेरा नाम पुकारा था।

MR. CHAIRMAN: Sorry, I think, he has given a wrong notice. ..*(Interruptions)*.. Shri Satish Chandra Misra.

SHRI SATISH CHANDRA MISRA: Sir, with respect to Question No. 481, most of the drugs, which are life saving drugs, are being spuriated and they are being sold and manufactured as spuriated drugs. ..*(Interruptions)*..

MR. CHAIRMAN: Order please. ..*(Interruptions)*..

SHRI SATISH CHANDRA MISRA: These life saving drugs are being spuriated because they are very costly. Now, costly drugs are being duplicated. I would like to ask the hon. Minister if the Government is having some scheme to see that subsidies are given to the life saving drugs which are costly drugs so that there is no duplication taken place of such drugs because only expensive drugs are being duplicated.

SHRI GULAM NABI AZAD: Sir, there are two types of drugs which are being counterfeited — one is costly drugs because if they counterfeit the costly drugs, they will make a lot of money; and the other is the drugs which are being recommended by the doctors for longer duration like diabetes drugs, cardio vascular drugs, malaria-related drugs, T.B. drugs or cancer drugs. These are the drugs which are normally counterfeited. So, as I have said, steps are being taken, and I do not think the Government could have or this Parliament could have taken it more seriously than it has taken and made very stringent laws. In so far as the issue of free drugs is concerned, I would like to say that in so far as the drugs are concerned, I think, across the globe, we are the cheapest drug producers in the world. Even otherwise, all the vaccination,

immunisation across the country is free of cost. I do not think, at this stage it will be possible for the Government to introduce more drugs. Except, of course, this Tamiflu, we are giving so far three drugs. So, I do not think that it will be possible for the Government to give all types of drugs free of cost. ..*(Interruptions)*..

श्री ईश्वर सिंह : सर, मेरे सवाल का जवाब नहीं दिया।...(**व्यवधान**)...

श्री सभापति : आप बैठ जाइए, आपका टर्न नहीं है।...(**व्यवधान**)...

SHRI ABANI ROY: May I draw the attention of the Health Minister please? Sir, Livofloxacin cost us Rs. 20.61 per 10 tablets — this is our price — whereas Sanofi Aventis is Rs. 951 which is branded one. ..*(Interruptions)*..

MR. CHAIRMAN: Silence please.

SHRI ABANI ROY: Now, on the question of schedule 'M and GLP' that you have mentioned, you know that for this very high capital investment is required. And, Sir, from the side of the subordinate legislative committee, a report has been placed before the House. I would like to ask what steps have been taken by the Government to ensure the competitiveness of SME pharma units. As recommended by the Hathi Committee in 1978 to phase out branded medicines. The said SME unit was closed due to financial burden imposed by you through Schedule M and GLP.

SHRI GHULAM NABI AZAD: Sir, I am afraid I won't be able to answer this specific question concerning a specific drug. I will send the answer to the hon. Member.

*482. [The questioner (Shri Varinder Singh Bajwa) was absent. For answer *vide* page 20-22 *infra*.]

Treatment of Swine Flu patients

*483. SHRI VIJAY JAWAHARLAL DARDA:††
SHRIMATI SYEDA ANWARA TAIMUR:

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

(a) whether in view of the global menace of Swine Flu, fool-proof capabilities have been developed to treat patients who are contracting this virus from human-to-human transmissions;

(b) if so, how many suspected patients arrived from abroad and also those who contracted this virus in India through infection from such patients, were treated till 30 June, 2009; and

(c) whether any fatalities of Swine Flu patients have happened till 30 June, 2009?

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI GHULAM NABI AZAD): (a) to (c) A statement is laid on the Table of the House.

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††The question was actually asked on the floor of the House by Shri Vijay Jawaharlal Darda.