GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

LOK SABHA
UNSTARRED QUESTION No. 2472
TO BE ANSWERED ON THE 2nd January, 2018

Medicine Quality

2472. SHRIMATI KOTHAPALLI GEETHA:

Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:

(a) whether it is a fact that as per a recent released report, the medicines available in the hospitals and markets for various diseases are of low quality and potency and there is no proper monitoring of such medicines in the market to detect the duplicate medicines, if so, the details thereof and the reasons therefor;
(b) whether medicines like oral rehydration salt, stents, medicines for fever, vomiting and loose motions which are being supplied by Government and private hospitals are of low quality or duplicate medicines, if so, the details thereof and the reasons therefor;
(c) whether there is no proper Regulation and Acts to detect the duplicate medicines and even though such laws exist in some States, it is very weak and ineffective, if so, the details thereof and the reasons for such situation; and
(d) whether in some States like Himachal Pradesh, Telangana, Uttarakhand, Gujarat, Sikkim, Daman and Diu, Haryana, etc., duplicate medicines are being supplied to patients thereby putting therein lives in danger, if so, the details thereof and the reasons therefor?

ANSWER

MINISTER OF STATE IN THE MINISTRY OF ROAD TRANSPORT AND HIGHWAYS; MINISTRY OF SHIPPING AND MINISTRY OF CHEMICALS AND FERTILIZERS (SHRI MANSUKH L. MANDAVIYA)

(a): In the year 2014-16 a National Drug Survey was conducted to assess the extent of Not of Standard Quality (NSQ)/Spurious drugs in the country. Details of no. of samples tested under the survey and the findings are as under:

Year	No. of drugs samples tested	No. of drugs samples declared not of standard quality	% of drugs samples declared not of standard quality	No. of drugs samples declared spurious/ adulterated	% of drugs samples declared spurious/ adulterated
2014-16	47012	1850	3.16	13	0.0245

Moreover, in the said survey, 10.02% (total 839 out of the 8369 samples) of the drug samples drawn from Government sources were found Not of Standard Quality (NSQ). The test Reports of the drug samples declared as Not of Standard Quality (NSQ were forwarded to concerned State Licensing Authorities with a request to take appropriate action and also to take legal samples of same batch of drugs for testing.
There is no separate mechanism/ provisions under the Drugs & Cosmetics Act, 1940 and Rules, 1945 for monitoring the quality of medicines supplied to Govt. Agencies. Whether the drugs is

for Govt. supply or for domestic marketing, manufacturing sale and distribution of drugs in the country are regulated under the provisions of Drugs & Cosmetics Act, 1940 and Rules, 1945 made thereunder through a system of licensing and inspection. License for manufacturing, sale and distribution of Drugs are granted by State Licensing Authorities appointed by respective State Governments. Licensees are required to comply with all the conditions of license and follow Good Manufacturing Practices (GMP) to ensure that the drugs manufactured by them are safe and of standard quality. One of the conditions of the license is that licensee shall either in his own lab or in any other laboratory approved by the Licensing Authority test each batch of the raw material used by him for the manufacture of products and also each batch of the final product and shall maintain records showing the particulars in respect of such tests. The State Licensing Authorities are empowered to take action in case of any violation of above requirements.

The Government of India has taken various steps to check the quality of drugs manufactured, sale and distribution in the country. Details are as under:

1. The Drugs and Cosmetics Act, 1940 was amended under Drugs & Cosmetics (Amendment) Act 2008 to provide stringent penalties for manufacture of spurious and adulterated drugs. Certain offences have also been made cognizable and non-bailable.
2. The States / UTs were requested to set up special Courts for trial of offences under the Drugs and Cosmetics Act for speedy disposal. So far, 22 States have already set up designated special Courts.
3. A Whistle Blower Scheme was announced by the Government of India to encourage vigilant public participation in the detection of movement of spurious drugs in the country. The scheme provides for suitably rewarding the informers for providing concrete information to the regulatory authorities in respect of movement of spurious drugs. The details of policy are available at the website of CDSCO (www.cdsco.nic.in).
4. Guidelines for taking action on samples of drugs declared spurious or not of standard quality in the light of enhanced penalties under the Drugs & Cosmetics (Amendment) Act, 2008 were forwarded to the State Drugs Controllers for uniform implementation.
5. The inspectorate staffs have been instructed to keep a vigil and draw samples of drugs for test and analysis to monitor the quality of drugs moving in the country.
6. The number of sanctioned posts in Central Drugs Standard Control Organization (CDSCO) has been increased from 111 in 2008 to 510 in 2017.
7. The Government has decided to strengthen both the Central and States drug regulatory system during the 12th Five Year Plan enabling them to keep more effective watch on unscrupulous elements indulging in unlawful activities relating to quality of drugs. The Cabinet Committee on Economic Affairs (CCEA) has approved the proposal for strengthening the drug regulatory system in the country, both under the Central and State Governments at a total expenditure of Rs. 1750 crores. Out of this, Rs. 850 crore is the Central Government's share. The share of the Centre and the States in case of state component will be in the ratio of 60:40 for all States except Jammu and Kashmir, Himachal Pradesh, Uttarakand, Sikkim and North-Eastern States, for which the ratio will be 90:10.
8. The Drugs and Cosmetics Rules, 1945 have been amended vide Gazette notification no. G.S.R. 1337 (E) dated 27.10.2017, making it mandatory that before the grant of manufacturing license, the manufacturing establishment is to be inspected jointly by the Drugs Inspectors of Central Government and State Government. Further, the licensed manufacturing premises shall be inspected jointly by the Drugs Inspectors of Central Government and State Government to verify the compliance with the conditions of license and the provisions of the Drugs & Cosmetics Act and Rules for not less than once in three years or as needed as per risk based approach.

(b): Central Drugs Standard Control Organization (CDSCO) has not received any such report that medicines like oral rehydration salt, stents, medicines for fever, vomiting and loose motions which are being supplied by Government and private hospitals are of low quality or duplicate medicines.

(c) & (d): Manufacturing sale and distribution of drugs in the country are regulated under the provisions of Drugs & Cosmetics Act, 1940 and Rules, 1945 made thereunder through a system of licensing and inspection. License for manufacturing, sale and distribution of Drugs are granted by State Licensing Authorities appointed by respective State Governments. Licensees are required to comply with all the condition of license and follow Good Manufacturing Practices (GMP) to ensure that the drugs manufactured by them are safe and of standard quality.

The State Licensing Authorities are empowered to take action on violation of any conditions of the license. As per information received from States/U.Ts Drugs Controllers, No. of drug samples tested, no. of drug samples reported spurious/ adulterated and sub-standard drugs, value of drugs seized and action taken against the offenders during each of the last three years is enclosed as Annexure.

Annexure referred to in the answer to part (c) & (d) to the Lok Sabha Unstarred Q. No. 2472 for 02.01.2018

Number of samples tested and enforcement actions taken by State Drugs Controller during April 2014-2015										
S. No.	States	No. of drugs samples tested	No. of drugs samples declared not of standard quality	No. of drugs samples declared spurious / adultrated	No. of prosecution launched for manufacturing , sale and distribution of spurious/ adulterated drugs	No. of cases (as mentioned in the earlier column) decided	No. of persons arrested	Approx value of drug seized	No. of Raids conducted	Action taken w.r.t. no. of raids conducted
1	Himachal Pradesh	881	31	Nil	Nil	NA	NA	NA	Nil	NA
2	Telangana	3716	35	Nil	Nil	Nil	Nil	94,20, 600 (in the month of April)	Nil	Nil
3	Uttarakhand	182	10	Nil	Nil	Nil	Nil	Nil	4	Manufacturing license of 06 mfg. units has been suspended for further order sure due found violation of provisions of D&C Act & Rules thereunder
4	Gujarat	11300	499	5	5	Nil	Nil	Nil	5	Under investigation
5	Sikkim	87	1	1	Nil	Nil	Nil	Nil	Nil	Nil
6	Daman & Diu	60	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil
7	Haryana	2150	25	2	2	Nil	Nil	Nil	8306	101 – License Cancelled 187- License suspended 12-cpirt case launched 01- Warning issued 118- under investigation where show cause notice issued 01-FIRs Registered

Number of samples tested and enforcement actions taken by State Drugs Controller during April 2015-2016										
S. No.	States	No. of drugs samples tested	No. of drugs samples declared not of standard quality	No. of drugs samples declared spurious / adultrated	No. of prosecution launched for manufacturing , sale and distribution of spurious/ adulterated drugs	No. of cases (as mentioned in the earlier column) decided	No. of persons arrested	Approx value of drug seized	No. of Raids conducted	Action taken w.r.t. no. of raids conducted
1	Himachal Pradesh	936	24	Nil	1	Nil	Nil	Mostly Govt. Supply	1	a) Under Investigation b) FIR Filed
2	Telangana	2462	25	3	2	-	-	661000/-	309	3-NSQ 2- Under investigation 20 Seized under investigation 7prosecution launched and others are under departmental Action taken
3	Uttarakhand	88	17	-	-	-	-	-	-	-
4	Gujarat	13425	448	8	42	0	0	0	18	Under investigation
5	Sikkim	105	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil
6	Daman & Diu	7	Nil	Nil	NA	Nil	Nil	Nil	Nil	NA
7	Haryana	2262	38	3	3	Nil	1	Nil	65	License suspended/ cancelled/prosecution launched, under Drugs and Cosmetics Act.

Number of samples tested and enforcement actions taken by State Drugs Controller during April 2016-2017										
S. No.	States	No. of drugs samples tested	No. of drugs samples declared not of standard quality	No. of drugs samples declared spurious / adultrated	No. of prosecution launched for manufacturing , sale and distribution of spurious/ adulterated drugs	No. of cases (as mentioned in the earlier column) decided	No. of persons arrested	Approx value of drug seized	No. of Raids conducted	Action taken w.r.t. no. of raids conducted
1	Himachal Pradesh	1001	36	5	Nil	Nil	Nil	Nil	Nil	Nil
2	Telangana	2619	39	Nil	Nil	Nil	Nil	Nil	Nil	Nil
3	Uttarakhand	217	22	Nil	Nil	Nil	Nil	Nil	5	Nil
4	Gujarat	11071	535	22	2	Nil	Nil	Nil	3	Under investigation
5	Sikkim	102	3	Nil	Nil	Nil	Nil	Nil	Nil	Nil
6	Daman & Diu	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil
7	Haryana	1901	12	1	5	1	Nil	Nil	6890	-

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