

**GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS**

LOK SABHA

UNSTARRED QUESTION NO. 3295

TO BE ANSWERED ON 6th December, 2016

Generic Drug Sale

3295. SHRI P.R. SUNDARAM:

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

- (a) whether the Pharmaceutical sector is suffering due to too much counter sale of generic drugs and medicines by drug stores and medical shops;
- (b) if so, the details thereof and the corrective steps taken by the Government in this regard;
- (c) the modalities, guidelines and norms chalked out by the Government to check, monitor and curb the distribution and sale of spurious drugs and expired medicines in the country; and
- (d) the total quantum and value of spurious drugs and expired medicines found/detected from the pharmaceutical market across the country during the last three years and the current year?

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) & (b): No, Madam. As per the report of Working Group on Drugs and Pharmaceutical Industry 12th Five Year Plan (2012-2017), the Indian Pharmaceutical Industry is ranked 3rd globally in volume and 14th in value, supplying around 10% of total global production.

(c): The Govt. of India has taken/taking the following steps to improve the quality of drugs in the country:-

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 by setting of special Courts.

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.cdsc0.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 474 in 2016.

7. The testing capacities of Central Drugs Testing Laboratories under CDSCO are being constantly strengthened to expedite testing of drug samples in the country.

(d): Isolated cases of spurious and expired drugs have been detected in the country. The State/UT-wise data on spurious drugs found to be detected in the country during last three years and current year, as per information received from various State/U.T. Drugs Controllers is enclosed as **Annexure-A**.

Such data in respect of expired drugs is enclosed as **Annexure-B**.

Number of drugs declared not of standard quality, spurious/adulterated and approx value of drugs seized during April 2013- March 2014

S.No.	States	No. of drugs samples declared not of standard quality	No. of drugs samples declared spurious/ adulterated	Approx. value of drug seized (Rs.)
1	Andhra Pradesh	61	12	134.68 lakhs
2	Arunachal Pradesh	6	Nil	NA
3	Assam	39	Nil	Nil
4	Bihar	52	4	50,000
5	Goa	34	Nil	Nil
6	Gujarat	567	32	Nil
7	Haryana	52	3	Apprx. 2Lakh
	Himachal Pradesh	28	1	NA
9	Jammu & Kashmir	153	6 (03-spurious, 03-Adultrated)	9969962
10	Karnataka	292	4	Nil
11	Kerala	152	Nil	Nil
12	Madhya Pradesh	75	Nil	Nil
13	Maharashtra	466	19	37.85 lakhs
14	Manipur	Nil	Nil	Nil
15	Meghalaya	1	Nil	Nil
16	Mizoram	Nil	Nil	12 lakhs
17	Nagaland	4	Nil	Nil
18	Orissa	74	2	59775
19	Punjab	106	3	7566079
20	Rajasthan	38	7	1318489
21	Sikkim	Nil	Nil	Nil
22	Tamilnadu	314	6	13256
23	Tripura	35	2	Nil
24	Uttar Pradesh	336	5	4536820
25	West Bengal	22	Nil	300000
26	Pondicherry	Nil	Nil	Nil
27	Andaman & Nicobar	Nil	Nil	Nil
28	Chandigarh	3	None	None
29	Delhi	17	5	NA
30	Dadra & Nagar Haveli	Nil	Nil	Nil
31	Daman & Diu	Nil	Nil	Nil
32	Lakshadweep	Nil	Nil	Nil
33	Chattisgarh	11	Nil	Nil
34	Jharkhand	59	Nil	Nil
35	Uttarakhand	31	7	Not Yet calculated
	Total	3028	118	424.67 lacs

Number of drugs declared not of standard quality, spurious/adulterated and approx value of drugs seized during April 2014- March 2015

S.No.	States	No. of drugs samples declared not of standard quality	No. of drugs samples declared spurious/ adulterated	Approx. value of drug seized (Rs.)
1	Andhra Pradesh	10	4	1010635
2	Arunachal Pradesh	7	1 (Misbranded)	Nil
3	Assam	39	Nil	Nil
4	Bihar*	11	Nil	Nil
5	Goa	11	Nil	Nil
6	Gujarat	499	5	Nil
7	Haryana	25	2	Nil
	Himachal Pradesh	31	Nil	NA
9	Jammu & Kashmir	42	1	1,865,950
10	Karnataka	302	527095
11	Kerala	103	Nil	Nil
12	Madhya Pradesh	27	1	Nil
13	Maharashtra	420	25	35006352
14	Manipur	Nil	Nil	Nil
15	Meghalaya	1	Nil	Nil
16	Mizoram	Nil	Nil	Nil
17	Nagaland	Nil	Nil	Nil
18	Orissa	98	1	97,240
19	Punjab	61	8	2218274
20	Rajasthan	97	3	2929097
21	Sikkim	1	Nil	Nil
22	Tamilnadu	387	2	Nil
23	Tripura	22	Nil	Nil
24	Uttar Pradesh	1384	28	4833868
25	West Bengal	22	1	Nil
26	Pondicherry	Nil	Nil	Nil
27	Andaman & Nicobar	Nil	Nil	Nil
28	Chandigarh	3	None	183000
29	Delhi	1	1	19000
30	Dadra & Nagar Haveli	Nil	Nil	Nil
31	Daman & Diu	Nil	Nil	Nil
32	Lakshadweep	Nil	Nil	Nil
33	Chattisgarh	24	Nil	Nil
34	Jharkhand	29	Nil	140000
35	Uttarakhand	10	Nil	Nil
36	Telangana	35	Nil	94,20,600(in the month of April
Total		3702	83	58251111

Number of drugs declared not of standard quality, spurious/adulterated and approx value of drugs seized during 1st April 2016 to 30th September 2016

S.No.	States	No. of drugs samples declared not of standard quality	No. of drugs samples declared spurious/ adulterated	Approx. value of drug seized
1	Andhra Pradesh	17	Nil	10470763
2	Arunachal Pradesh	19	4 (Spurious 3 + misbranded 1)	NA
3	Assam	8	Nil	Nil
4	Bihar	11	Nil	26311817
5	Goa	10	Nil	Nil
6	Gujarat	208	5	Nil
7	Haryana	8	2	25583.12
8	Himachal Pradesh	18	5	Nil
9	Jammu & Kashmir	23	Nil	Nil
10	Karnataka	219	Nil	97,937
11	Kerala	66	Nil	Nil
12	Madhya Pradesh			
13	Maharashtra			
14	Manipur	Nil	Nil	Nil
15	Meghalaya	Nil	Nil	Nil
16	Mizoram	4	Nil	Nil
17	Nagaland	Nil	Nil	Nil
18	Orissa	54	Nil	Nil
19	Punjab	28	11	1,699,200
20	Rajasthan	62	9	199428.00
21	Sikkim	3	Nil	Nil
22	Tamilnadu	235	1	Nil
23	Tripura	3	Nil	Nil
24	Uttar Pradesh	423 (Sub-std.-113+ Misbranded-310)	3	5302948/-
25	West Bengal	20	Nil	Nil
26	Pondicherry	Nil	Nil	Nil
27	Andaman & Nicobar	Nil	Nil	Nil
28	Chandigarh	1	Nil	Price of four portions seized on form 17 Rs. 622/- of drugs declared as not of standard quality
29	Delhi	6	Nil	15000
30	Dadra & Nagar Haveli	Nil	Nil	Nil
31	Daman & Diu			
32	Lakshadweep	Nil	Nil	Nil
33	Chattisgarh	Nil	Nil	Nil
34	Jharkhand	2	Nil	-
35	Uttarakhand	20	Nil	Nil
36	Telangana	19	Nil	Nil
Total		1487	40	4,41,23,298.12

Number of drugs declared not of standard quality, spurious/adulterated and approx value of drugs seized during April 2015- March 2016

S.No.	States	No. of drugs samples declared not of standard quality	No. of drugs samples declared spurious/ adulterated	Approx. value of drug seized (Rs.)
1	Andhra Pradesh	113	90	1614601
2	Arunachal Pradesh	17	2 (1 Surious + 1 misbranded)	Nil
3	Assam	21	Nil	Nil
4	Bihar***	3	Nil	Nil
5	Goa	8	Nil	Nil
6	Gujarat	448	8	0
7	Haryana	38	3	Nil
8	Himachal Pradesh	24	Nil	Mostly Govt. Supply
9	Jammu & Kashmir	54	1	2,704,443
10	Karnataka	563	Nil	Value of NSQ drug seized Rs. 33,66,850
11	Kerala	152	Nil	Nil
12	Madhya Pradesh	24	Nil	Nil
13	Maharashtra	351	31	Rs.1,01,58,938/-
14	Manipur	Nil	Nil	Nil
15	Meghalaya	16	Nil	Nil
16	Mizoram	7 (1 Sample is Misbranded)	Nil	Rs. 15 Lacs.
17	Nagaland	1	Nil	Nil
18	Orissa*	93	1	641583/- Spurious drugs
19	Punjab	165	37	2,51,06,982/-
20	Rajasthan	208	3	2026.50
21	Sikkim	Nil	Nil	Nil
22	Tamilnadu	478	4	Nil
23	Tripura	16	Nil	Nil
24	Uttar Pradesh	782	45	Rs 85,32,071/-
25	West Bengal	24	1	Nil
26	Pondicherry	Nil	Nil	Nil
27	Andaman & Nicobar	Nil	Nil	Nil
28	Chandigarh	5	Nil	Rs. 22,976/-
29	Delhi	9	5	10 Lakhs
30	Dadra & Nagar Haveli	Nil	Nil	Nil
31	Daman & Diu	Nil	Nil	Nil
32	Lakshadweep	Nil	Nil	Nil
33	Chattisgarh	12	Nil	2,000
34	Jharkhand	29	Nil	-
35	Uttarakhand	17	-	-
36	Telangana	25	3	661000/-
Total		3703	234	55313470.5 + Govt. Supply

(*) = Data as on April 2015 to Feb 2016

(**)= Includes 02 raids with Delhi Police officers

(***)= data as on 1st April 2015-30th Sept. 2015)

Statement Showing Quantity of expired drugs seized and approximate value of drugs seized (for year 2013-14)			
S.No.	States	Quantity of expired drugs seized	Approximate value of drugs seized (In Rs)
1	Andhra Pradesh	Nil	Nil
2	Arunachal Pradesh	Nil	Nil
3	Assam	Nil	Nil
4	Bihar *	Nil	Nil
5	Goa	Nil	Nil
6	Gujarat	Nil	Nil
7	Haryana	Nil	Nil
8	Himachal Pradesh	Nil	Nil
9	Jammu & Kashmir	15 Ampoules or various drugs other than Neogest	Rs. 4278
10	Karnataka	Nil	24
11	Kerala	50 no. of 60 drug items	Appr. Rs. 3059
12	Madhya Pradesh	Nil	Nil
13	Maharashtra	N.A	N.A
14	Manipur	Nil	Nil
15	Meghalaya	Nil	Nil
16	Mizoram	Nil	Nil
17	Nagaland	Nil	Nil
18	Orissa	37	4011
19	Punjab	9612 tabs, 03 syrups, 290 caps, 42 ORS Pouch	38,000
20	Rajasthan	Nil	Nil
21	Sikkim	Nil	Nil
22	Tamil Nadu	List enclosed	Rs. 9470
23	Tripura	Nil	Nil
24	Uttar Pradesh	Tablets and capsules of different companies	195000
25	West Bangal	Nil	Nil
26	Pondichery	Nil	Nil
27	Andaman & Nicobar Island	Nil	Nil
28	Chandigarh	Nil	Nil
29	Delhi	Nil	Nil
30	Dadra & Nagar Haveli	Nil	Nil
31	Daman & Diu	Nil	Nil
32	Lakshadweep	Nil	Nil
33	Chattisgarh	Nil	Nil
34	Jharkhand	Nil	Rs. 700
35	Uttarakhand	On raid further stock of expired drugs not found hence no seizure	Nil
36	Telangana	Nil	Nil
(*) Data received til September 2013			
Total		10012	254542

Statement Showing Quantity of expired drugs seized and approximate value of drugs seized (for year 2014-15)			
S.No.	States	Quantity expired drugs seized	Approximate value of drugs seized (In Rs)
1	Andhra Pradesh	20 varieties of drugs	20,000
2	Arunachal Pradesh	Nil	does not arise
3	Assam	Nil	Nil
4	Bihar *	557 units	40,000
5	Goa	Nil	Nil
6	Gujarat	Nil	Nil
7	Haryana	Nil	Nil
8	Himachal Pradesh	NA	NA
9	Jammu & Kashmir	15 Ampoules of various drugs other than Neogest	4278
10	Karnataka
11	Kerala	Nil	Nil
12	Madhya Pradesh	Nil	Nil
13	Maharashtra	NA	NA
14	Manipur	Nil	Nil
15	Meghalaya	Does not arise	Does not arise
16	Mizoram	Nil	Nil
17	Nagaland	Nil	Nil
18	Orissa	Nil	Nil
19	Punjab	Data Not Available at HQ	73,264
20	Rajasthan	0	0
21	Sikkim	Nil	Nil
22	Tamil Nadu	NA	Nil
23	Tripura	Nil	0
24	Uttar Pradesh *	309x 10 Tablets of various brands 38x10 Capsules of various brands 14x5ml LVP& 5x40 Condoms	15000
25	West Bangal	NA	NA
26	Pondichery	Nil	Nil
27	Andaman & Nicobar Island	Nil	Nil
28	Chandigarh	None	None
29	Delhi	Nil	Nil
30	Dadra & Nagar Haveli	Nil	Nil
31	Daman & Diu *	NA	NA
32	Lakshadweep	Nil	Nil
33	Chattisgarh	5 cartoon	30000
34	Jharkhand	1 box & 523 tab	Nil
35	Uttarakhand	Nil	Nil
36	Telangana	Nil	Nil
(*) Data received til September 2014			
Total		approx 4600	182542

Statement Showing Quantity of expired drugs seized and approximate value of drugs seized (for year 2015-16)

S.No.	States	Quantity expired drugs seized	Approximate value of drugs seized (In Rs)
1	Andhra Pradesh	2	3500/-
2	Arunachal Pradesh	Nil	Nil
3	Assam	Nil	Nil
4	Bihar**	Nil	Nil
5	Goa	Nil	Nil
6	Gujarat	Nil	Nil
7	Haryana	-	Approx. 1,90,000/-
8	Himachal Pradesh	Nil	Nil
9	Jammu & Kashmir	15 Rolls expired cotton & other expired drugs	5800
10	Karnataka	Nil	Nil
11	Kerala	7 items of varying quantity	Appxo. 3576.54 Rs.
12	Madhya Pradesh	Nil	Nil
13	Maharashtra	Nil	Nil
14	Manipur	Nil	Nil
15	Meghalaya	Nil	Nil
16	Mizoram	Nil	Nil
17	Nagaland	Nil	Nil
18	Orissa*	Nil	Nil
19	Punjab	5 itmes	41,69,772/-
20	Rajasthan	-	-
21	Sikkim	Nil	Nil
22	Tamil Nadu	75 items of varying quantity	Rs. 2000000/-
23	Tripura	91 items	Not Calculated
24	Uttar Pradesh	About 76 Gunny bages of expired medicine	5 lakhs
25	West Bangal	Nil	Nil
26	Pondicherry	Nil	Nil
27	Andaman & Nicobar Island	Nil	Nil
28	Chandigarh	Nil	Nil
29	Delhi	Nil	Nil
30	Dadra & Nagar Haveli	Nil	Nil
31	Daman & Diu	Nil	Nil
32	Lakshadweep	Nil	Nil
33	Chhattisgarh	1 items	25000
34	Jharkhand	-	Approximate 4000
35	Uttarakhand	-	-
36	Telangana	variety of drugs seized	1,17,800/-
Total		272	7019448.54

(*) = Data as on April 2015 to Feb 2016

(**) = Data as on 1st April to 30 th sept. 2015)

Statement Showing Quantity of expired drugs seized and approximate value of drugs seized (for 1 april to 30 sep 2016)

S.No.	States	Quantity expired drugs seized	Approximate value of drugs seized (In Rs)
1	Andhra Pradesh	Nil	Nil
2	Arunachal Pradesh	Does not arise	Does not arise
3	Assam	Nil	Nil
4	Bihar	51	819034
5	Goa	Nil	Nil
6	Gujarat	Nil	Nil
7	Haryana	Nil	Nil
8	Himachal Pradesh	Nil	Nil
9	Jammu & Kashmir	1 Item (09 vials of Inj. Caspolungin Acetatae)	112500
10	Karnataka	Nil	Nil
11	Kerala	Nil	Nil
12	Madhya Pradesh		
13	Maharashtra		
14	Manipur	Nil	Nil
15	Meghalaya	Does not arise	Does not arise
16	Mizoram	Nil	Nil
17	Nagaland	Nil	Nil
18	Orissa	Nil	Nil
19	Punjab	Nil	Nil
20	Rajasthan	Nil	Nil
21	Sikkim	Nil	Nil
22	Tamil Nadu	Nil	Nil
23	Tripura	Nil	Nil
24	Uttar Pradesh	Nil	Nil
25	West Bangal	Nil	Nil
26	Pondicherry	Nil	Nil
27	Andaman & Nicobar Island	Nil	Nil
28	Chandigarh	Nil	Nil
29	Delhi	Nil	Nil
30	Dadra & Nagar Haveli	Nil	Nil
31	Daman & Diu		
32	Lakshadweep	Nil	Nil
33	Chhattisgarh	Nil	Nil
34	Jharkhand	-	approx 3000
35	Uttarakhand	Nil	Nil
36	Telangana	Nil	Nil
Total		52	934534