

GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

LOK SABHA

UNSTARRED QUESTION No. 2582

TO BE ANSWERED ON THE 2nd August, 2016

Spurious Drugs

2582. SHRI B. SRIRAMULU:

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

- (a) whether the Government is keeping adequate tab on the production of spurious drugs by pharmaceutical companies;
- (b) if so, the details of such cases detected during each of the last three years and the current year, company-wise;
- (c) whether any stringent action has been taken by the Government on the Pharma companies engaged in producing sub-standard drugs affecting the health of the people; and
- (d) if so, the details thereof during the said period, company-wise?

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): Yes, Madam.

(b): A statement giving number of samples of drugs tested and enforcement action taken by State Drug Controller during 2013-14, 2014-15 and 2015-16 is annexed.

(c) & (d): All the cases referred to in Part (b) above were investigated and FIR, Prosecution, Suspension/Cancellation of licenses were done where found guilty. Company wise detail is not available with the Department of Pharmaceuticals.

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STATEMENT REFERRED TO IN LOK SABHA UNSTARRED QUESTION NUMBER 2582 FOR 02.08.2016**2013-14**

Number of samples tested and enforcement actions taken by State Drugs Controller during April 2013- March 2014										
S.No.	States	No. of drugs samples tested	No. of drugs samples declared not of standard quality	No. of drugs samples declared spurious/ adulterated	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	Andhra Pradesh	7343	61	12	12	Under trial	Not given	134.68 lakhs	1645 shops	SO issued -950 Cancellations-300 Warnings-112
2	Arunachal Pradesh	183	6	Nil	NA	NA	NA	NA	NA	NA
3	Assam	1097	39	Nil	Nil	Nil	Nil	Nil	Nil	Nil
4	Bihar	1137	52	4	1	Nil	Nil	50,000	80	explanation on- 69 suspended -27
5	Goa	590	34	Nil	Nil	Nil	Nil	Nil	Nil	Nil
6	Gujarat	9713	567	32	Nil	Nil	1	Nil	13	Under investigation
7	Haryana	2494	52	3	3	Nil	1	Apprx. 2Lakh	6839	Drug License suspndd -378 Drug Lice. Cancelled-179 Court case launed -27 FIR got registered -9
8	Himachal Pradesh	751	28	1	1(seizure in 2011)	Nil	Nil	NA	Nil	NA

9	Jammu & Kashmir	4550	153	6 (03-spurious, 03-Adultrated)	6 (03-spurious, 03-Adultrated)	sub-judice	Nil	9969962	Nil	Nil
10	Karnataka	9366	292	4	1	Nil	Nil	Nil	Nil	Nil
11	Kerala	4557	152	Nil	Nil	Nil	Nil	Nil	Nil	NA
12	Madhya Pradesh	1370	75	Nil	Nil	Nil	Nil	Nil	Nil	Nil
13	Maharashtra	6097	466	19	11	Nil	5	37.85 lakhs	17	7
14	Manipur	7	Nil	Nil	Nil	Nil	Nil	Nil	Nil	NA
15	Meghalaya	31	1	Nil	Initiated	Nil	Nil	Nil	Nil	Nil
16	Mizoram	115	Nil	Nil	Nil	Nil	6	12 lakhs	6	prosecuted the arrested persons and the seized drugs were destroyed
17	Nagaland	266	4	Nil	Nil	Nil	Nil	Nil	Nil	Nil
18	Orissa	4226	74	2	1	Nil	Nil	59775	1475	Raids conducted and steps taken
19	Punjab	3449	106	3	1	42	Nil	7566079	1210	About 630 drug license suspended and 12 drug license wer cancelled
20	Rajasthan	1516	38	7	7	2	1	1318489	1915	147
21	Sikkim	109	Nil	Nil	Nil	Nil	NA	Nil	Nil	Nil
22	Tamilnadu	8356	314	6	4	Nil	Nil	13256	154	72 sanction orders have been issued for launching prosecutions before the concerned court
23	Tripura	798	35	2	1	Nil	Nil	Nil	Nil	NA
24	Uttar Pradesh	2068	336	5	120	Not available	68	4536820	1188	51 FIR lodge
25	West Bengal	894	22	Nil	Nil	Nil	3	300000	10	3
26	Pondicherry	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil
27	Andaman & Nicobar	3, results are awaited	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil

28	Chandigarh	100	3	None	None	None	None	None	4	Found Satisfactory
29	Delhi	166	17	5	Nil	Nil	Nil	NA	NA	NA
30	Dadra & Nagar Haveli	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil
31	Daman & Diu	33	Nil	Nil	Nil	NA	Nil	Nil	Nil	NA
32	Lakshadweep	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil
33	Chattisgarh	520	11	Nil	Nil	Nil	Nil	Nil	Nil	Nil
34	Jharkhand	402	59	Nil	63	Nil	1	Nil	4	2
35	Uttarakhand	405	31	7	2	Nil	Nil	Not Yet calculated	7	License suspended 3 and canceled 1
Total		72712	3028	118	237	44	86	424.67 lacs	14567	-----

2014-15

Number of samples tested and enforcement actions taken by State Drugs Controller during April 2014-March 2015										
S.No.	States	No. of drugs samples tested	No. of drugs samples declared not of standard quality	No. of drugs samples declared spurious/ adulterated	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	Andhra Pradesh	1270	10	4	Nil	Nil	Nil	1010635	505	Warnings issued-6, Sos issued-697, SCNS issued-198
2	Arunachal Pradesh	272	7	1 (Misbranded)	Nil	Nil	Nil	Nil	Nil	Nil
3	Assam	767	39	Nil	Nil	Nil	Nil	Nil	Nil	Nil
4	Bihar*	682	11	Nil	Nil	Nil	Nil	Nil	398	158
5	Goa	473	11	Nil	1	Nil	Nil	Nil	Nil	Nil
6	Gujarat	11300	499	5	5	Nil	Nil	Nil	5	Under investigation
7	Haryana	2150	25	2	2	Nil	Nil	Nil	8306	101- License Cancelled 187- License Suspended 12- Court case launched 01- warning issued 118- under investigation where

										Show cause notice issued 01- FIRs Registered
8	Himachal Pradesh	881	31	Nil	Nil	NA	NA	NA	Nil	NA
9	Jammu & Kashmir	3478	42	1	Prosecution permission granted & the same about to file	Nil	Nil	18,65,950	Nil	Nil
10	Karnataka	6818	302	3	527095
11	Kerala	4496	103	Nil	Nil	Nil	Nil	Nil	Nil	Nil
12	Madhya Pradesh	1761	27	1	Nil	Nil	Nil	Nil	Nil	Nil
13	Maharashtra	4406	420	25	01 (2 samples, 1 prosecution order. 01 prosecution filed) (in all 15 cases 13 prosecutionorder are issued) 11 sample,11 prosecution order 2 sample, 1 prosecution order 2 sample ,1 prosecution order	3	13	35006352	33	2 FIR launched 7 prosecution launched 19 under investigation, prosecution to be filed
14	Manipur	26	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil
15	Meghalaya	57	1	Nil	Nil	Nil	Nil	Nil	Nil	Nil
16	Mizoram	103	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil

17	Nagaland	56	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil
18	Orissa	3915	98	1	04 nos of seizure have been made during 2013-14 and 02 nos of seizure have been made during 2014-15	Nil	Nil	97,240	801(upto Feb 2015)	(i) S.C.N. under rule 66 (1) are being issued against the I/R submitted by the D.I. after conducting raid. (ii) Steps have been taken for drug recall of N.S.Q. drugs under intimation to concerned D.C./F.D.A. for further action at their end and to send their action taken report along with investigation report for finalisation of further action against manufacturers with due recommendation of the screening committee of the State so constituted in compliance to guidelines of Central Govt (iii) .No. of seizure made: 23

19	Punjab	2628	61	8	Nil	Nil	Nil	2218274	2318	Action under process
20	Rajasthan	2167	97	3	14	1	4	2929097	316	28 and (one case accused Convicted for 7 years and Penalty 7 laks Rupees)
21	Sikkim	87	1	Nil	Nil	Nil	Nil	Nil	Nil	Nil
22	Tamilnadu	9498	387	2	2	Nil	Nil	Nil	240 raids have been conducted during the said peiod against the sales premises.	450 sanction orders have been issued for launching prosecutions before the concerned court.
23	Tripura	679	22	Nil	Nil	Nil	Nil	Nil	3	under process
24	Uttar Pradesh	10440	1384	28	122	0	68	4833868	1089	64 FIR were lodged and 68 persons were arrested
25	West Bengal	842	22	1	Nil	Nil	Nil	Nil	5	Nil
26	Pondicherry	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil
27	Andaman & Nicobar	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil
28	Chandigarh	153	3	None	None	None	None	183000	1	Prosecution to be launched
29	Delhi	29	1	1	Nil	Nil	Nil	19000	1	FIR Launched

30	Dadra & Nagar Haveli	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil
31	Daman & Diu	60	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil
32	Lakshadweep	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil
33	Chattisgarh	464	24	Nil	Nil	Nil	Nil	Nil	Nil	Nil
34	Jharkhand	343	29	Nil	2	6	Nil	140000	17	F.I.R. -04 Licence Cancelled-01 Licence Suspended-01
35	Uttarakhand	182	10	Nil	Nil	Nil	Nil	Nil	4	Manufacturing license of 06 mfg. units has been suspended for further order sure due found violatin of provisions of D & C Act & Rules thereunder.
36	Telangana	3716	35	Nil	Nil	Nil	Nil	94,20,600(in the month of April	Nil	Nil
Total		74199	3702	83	152	10	85	58251111	14042	---

2015-16

Number of samples tested and enforcement actions taken by State Drugs Controller during 1st April 2015 to 31st March 2016										
S.No.	States	No. of drugs samples tested	No. of drugs samples declared not of standard quality	No. of drugs samples declared spurious/ adulterated	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	Andhra Pradesh	2711	113	90	Nil	Nil	Nil	1614601	-	-
2	Arunachal Pradesh	231	17	2 (1 Surious + 1 misbranded)	Nil	Nil	Nil	Nil	Nil	Nil
3	Assam	795	21	Nil	Nil	Nil	Nil	Nil	Nil	Nil
4	Bihar***	354	3	Nil	Nil	Nil	3	Nil	33	FIR-03 Suspend-01 Cancaled-11 Prosecution-15
5	Goa	521	8	Nil	Nil	Nil	Nil	Nil	Nil	Nil
6	Gujarat	13425	448	8	42	0	0	0	18	Under Investigation
7	Haryana	2262	38	3	3	Nil	1	Nil	65	Licenses suspended/cancelled/prosecution launched, under Drugs and Cosmetics Act.

8	Himachal Pradesh	936	24	Nil	1	Nil	Nil	Mostly Govt. Supply	1	a) Under Investigation b) FIR filed
9	Jammu & Kashmir	2565	54	1	1	Nil	Nil	27,04,443	Nil	Nil
10	Karnataka	8086	563	Nil	1	02 Cases filed earlier decided during this period	Nil	Value of NSQ drug seized Rs. 33,66,850	Nil	Nil
11	Kerala	5220	152	Nil	Nil	Nil	Nil	Nil	Nil	Nil
12	Madhya Pradesh	1622	24	Nil	Nil	Nil	Nil	Nil	Nil	Nil
13	Maharashtra	3778	351	31	(31) In all cases, prosecution orders are issued	investigation in progress	1	Rs.1,01,58,938/-	14	-
14	Manipur	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil
15	Meghalaya	131	16	Nil	Nil	Nil	Nil	Nil	Nil	Nil
16	Mizoram	98	7 (1 Sample is Misbranded)	Nil	Nil	Nil	Nil	Rs. 15 Lacs.	Nil	Nil
17	Nagaland	25	1	Nil	Nil	Nil	Nil	Nil	Nil	Nil
18	Orissa*	3678	93	1	26	Nil	1	641583/- Spurious drugs	845	52 Seizure
19	Punjab	2791	165	37	3 Action under process in rest of cases	Under trial	2	2,51,06,982/-	416	3 court cases have been launched, 18 FIR have been lodged, Rest of the

										cases are under investigation
20	Rajasthan	3297	208	3	26	-	-	2026.50	-	-
21	Sikkim	105	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil
22	Tamilnadu	9842	478	4	3	Nil	Nil	Nil	555 raids have been conducted during the said period against the sales premises	460 Sanction orders have been issued for launching prosecutions before the concerned court (Cases detected before 01.04.2015)
23	Tripura	627	16	Nil	Nil	Nil	Nil	Nil	Nil	Nil
24	Uttar Pradesh	7326	782	45	119	Nil	48	Rs 85,32,071/-	1316	FIR-56, persons arrested-48, Total seizure-Rs.85,32,071/-
25	West Bengal	722	24	1	Nil	Nil	Nil	Nil	Nil	Nil
26	Pondicherry	84	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil
27	Andaman & Nicobar	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil
28	Chandigarh	151	5	Nil	Nil	Nil	Nil	Rs. 22,976/-	4	Two Prosecution launched against the firm in the Hon'ble Court & remaining three under investigation

29	Delhi	40	9	5	5	Nil	3	10 Lakhs	18 **	59 firms were found contravening various provision of D & C Rules, 1945. Action against erring firms has been initiated as per rules. In 2 cases sub-standard/spurious drugs worth approximately 59 lakhs were seized by delhi police and in one case drug (Oxytocin) worth 10 lakhs were seized.
30	Dadra & Nagar Haveli	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil
31	Daman & Diu	7	Nil	Nil	NA	Nil	Nil	Nil	Nil	NA
32	Lakshadweep	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil
33	Chattisgarh	33	12	Nil	Nil	Nil	Nil	2,000	2	Case is under investigation
34	Jharkhand	573	29	Nil	26	Nil	-	-	52	18 FIR
35	Uttarakhand	88	17	-	-	-	-	-	-	-
36	Telangana	2462	25	3	2	-	-	661000/-	309	3- NSQ 2-Under Investigation 20 Seized under investigation 7 Prosecution Launched and

										others are under departmental Action taken
	Total	74,586	3703	234	289	2	59	55313470.5 + Govt. Supply	3648	-
(*) = Data as on April 2015 to Feb 2016										
(**)= Includes 02 raids with Delhi Police officers										
(***)= data as on 1st April 2015-30th Sept. 2015)										