

**GOVERNMENT OF INDIA  
MINISTRY OF HEALTH AND FAMILY WELFARE  
DEPARTMENT OF HEALTH AND FAMILY WELFARE**

**RAJYA SABHA  
UNSTARRED QUESTION NO. 3634  
TO BE ANSWERED ON 27<sup>TH</sup> MARCH, 2018**

**MONITORING MECHANISM FOR QUALITY OF DRUGS**

**3634. SHRI T.K. RANGARAJAN:**

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

- (a) the mechanism Government has to monitor the quality and standards of various drugs and pharmaceutical companies appearing in the market;
- (b) if there is such mechanism, whether any malpractices of the drug companies have been found; and
- (c) if so, details thereof?

**ANSWER  
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND  
FAMILY WELFARE  
(SHRI ASHWINI KUMAR CHOUBEY)**

(a) to (c): The manufacture, sale and distribution of drugs in the country is regulated under the provisions of Drugs & Cosmetics Act, 1940 and Rules, 1945 thereunder through a system of licensing and inspection. Licenses for manufacture, sale and distribution of drugs are granted by the State Licensing Authorities (SLAs) appointed by respective State Governments. SLAs are legally empowered to take stringent action against violation of provision of the Act and Rules.

In order to ensure the quality of drugs in the country, both the Central Drugs Standard Control Organisation (CDSCO) and the state drug regulators pick up a large number of samples of drugs from all over the country and have them tested and analysed in the laboratories of the Central and State Governments. In a few cases, the samples tested and analysed do not meet the prescribed standards. The details of the drugs that do not meet the standards are immediately notified by the Central or State regulator concerned.

Number of drug samples tested, number of drug samples reported spurious/adulterated and sub-standard drugs and action taken against the offenders by the CDSCO in the last three years is enclosed as **Annexure-I** and by States/UTs is at **Annexure- II**.

Further, the Government is committed to ensuring that the quality, safety and efficacy of drugs are not compromised. With this in view, the Government has taken a series of measures including strengthening legal provisions, workshops and training programmes for manufacturers and regulatory officials and measures such as risk based inspections.

Number of drug samples tested and enforcement actions taken by CDSCO during the last three years

<b>S. No.</b>	<b>Year</b>	<b>No. of drugs samples tested</b>	<b>No. of drugs samples declared not of standard quality</b>	<b>No. of drugs samples declared spurious/ adulterated</b>	<b>No. of prosecution launched for manufacturing, sale and distribution of spurious/ adulterated drugs</b>	<b>No. of persons arrested</b>	<b>Approx. value of drug seized (Rs.)</b>	<b>No. of Raids Conducted</b>
1	2014-15	3605	121	Nil	13	Nil	Nil	48
2	2015-16	2897	115	5	38	4	21052298	42
3	2016-17	5207	146	Nil	21	Nil	3911850	56

# ANNEXURE - II

## 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
	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	3	13	35006352	33	2 FIR launched 7 prosecution launched 19 under investigation, prosecution to be filed

[illegible]

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	---

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/cancel led/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	invetigation 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

[illegible]

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	<b>289</b>	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)



**Number of samples tested and enforcement actions taken by State Drugs Controller during  
1st April, 2016 to 31th March, 2017**

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	2979	22	Nil	Nil	Nil	Nil	13567403	Nil	Nil
2	Arunachal Pradesh	47	1	Nil	Nil	Nil	Nil	Nil	Nil	Nil
3	Assam	745	43	Nil	Nil	Nil	Nil	Nil	Nil	Nil
4	Bihar*	397	11	Nil	Nil	6	16	26311817	78	47
5	Goa	534	17	Nil	Nil	Nil	Nil	Nil	Nil	Nil
6	Gujarat	11071	535	22	2	Nil	Nil	Nil	3	under Investigation
7	Haryana	1901	12	1	5	1	Nil	Nil	6890	-
8	Himachal Pradesh	1001	36	5	Nil	Nil	Nil	Nil	Nil	Nil
9	Jammu & Kashmir	2958	60	Nil	Nil	Nil	Nil	13983937	Nil	Nil
10	Karnataka	8217	468	Nil	2	Nil	Nil	21 Lakhs NSQ Drugs	-	Nil
11	Kerala	8934	140	Nil	Nil	Nil	Nil	Nil	Nil	Nil
12	Madhya Pradesh	1624	15	3	Nil	Nil	Nil	Nil	Nil	Nil
13	Maharashtra	4592	335	33	In all cases, prosecution orders are issued & In 4 cases prosecution are filed in the Court.	Nil	1	392235	10	7
14	Manipur*	19	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil
15	Meghalaya*	97	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil
16	Mizoram	79	8	Nil	Nil	Nil	Nil	Nil	Nil	Nil
17	Nagaland	22	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil
18	Orissa	4036	113	Nil	Nil	Nil	Nil	Nil	851	Nil
19	Punjab	2750	58	16	12 (Action under process in rest of cases)	1	3	17,71,725	1389	1 court case has been launched rest of the cases are under investigation
20	Rajasthan	2545	147	30	3	2	15	1615137.47	13	1- process in court for withdraw retesting request by manufacturers 12- under investigation
21	Sikkim	102	3	Nil	Nil	Nil	Nil	Nil	Nil	Nil
22	Tamilnadu	9510	392	4	6 #	Nil	Nil	Nil	447	370 #
23	Tripura	1151	10	Nil	Nil	Nil	Nil	Nil	Nil	Nil

24	Uttar Pradesh	7357	222	3	106	2	54	1,42,35,568	1119	FIR-57, persons arrested-54, Total seizure-Rs. 14235568
25	West Bengal	683	36	4	6	Nil	4	Nil	4	Nil
26	Pondicherry	3	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil
27	Andaman & Nicobar *	Nil	Nil	Nil	Nil	Nil	Nil	Nil	10	Nil
28	Chandigarh	86	2	Nil	Nil	Nil	Nil	Nil	Nil	Nil
29	Delhi	278	18	2	5	5	Nil	15000	35	Total 289 firms were inspected out of which 82 firms were found contravening various provisions of Drugs and Cosmetics Rules, 1945. Action has been initiated/ taken against erring firms as per Rules.
30	Dadra & Nagar Haveli	4	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil
31	Daman & Diu	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil
32	Lakshadweep	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil
33	Chattisgarh	15	2	Nil	Nil	Nil	Nil	468895	1	Case is under investigation
34	Jharkhand	148	13	Nil	6	Nil	13	2807000	66	Suspension-34 Prosecution - 35 Cancellation - 05 FIR -28
35	Uttarakhand	217	22	Nil	Nil	Nil	Nil	Nil	5	Nil
36	Telangana	2619	39	Nil	Nil	Nil	Nil	Nil	Nil	Nil
Total		76,721	2,780	123	186	17	106	7,72,68,717.5	10,921	-

(\*)= data as on 1st April 2016 to 30th Sept. 2016)

(#)= Figure indicates the number of cases detected before 01.04.2016