

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

**LOK SABHA  
UNSTARRED QUESTION NO. 4932  
TO BE ANSWERED ON 16<sup>TH</sup> DECEMBER, 2016**

**TRACK AND TRACE MECHANISM FOR MEDICINES**

**4932. SHRI BHARTRUHARI MAHTAB:  
SHRI SANJAY DHOTRE:  
DR. SATYAPAL SINGH:**

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

- (a) whether the Government has implemented the Track and Trace mechanism to check the authenticity of medicines in the country;
- (b) if so, the salient features of the system;
- (c) whether the cases of manufacturing spurious and adulterated drugs have come to the notice of the Government;
- (d) if so, the State/UT-wise details thereof during each of the last three years and the current year along with the action taken against such manufacturers; and
- (e) the other steps taken/being taken by the Government to keep a check on spurious medicines in the country?

**ANSWER  
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND  
FAMILY WELFARE  
(SHRI FAGGAN SINGH KULASTE)**

(a) & (b): The Ministry of Health & Family Welfare had, with a view to establish trackability and traceability of drugs, issued a draft notification issued on 03.06.2015 to make barcoding compulsory on the Primary, Secondary and Tertiary packs to be marketed in the country and invited objections and suggestions from the stakeholders. The notification was, however, not finalized keeping in view the reservations of manufacturers regarding high cost of bar coding.

(c) & (d): State/UT-wise details of 'Not of Standard Quality' (NSQ)/Spurious/adulterated drugs detected in the country along with the action taken thereon during last three years and the current year, as per the information received from various State/UT Drugs Controllers are given in **Annexure**.

(e): 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. These include:

- I. stringent penalties including making certain offences cognizable and non-bailable;

- II. establishment of special designated Courts for trial of offences under the Drugs and Cosmetics Act for speedy disposal of cases;
- III. announcement of a Whistle Blower Scheme to encourage vigilant public participation for detection of movement of spurious drugs in the country;
- IV. issuance of guidelines to the State Drugs Controllers for taking action on samples of drugs declared spurious, adulterated, misbranded or 'not of standard quality';
- V. instructions to the concerned staff to keep a vigil and draw samples of drugs for test and analysis for monitoring the quality of drugs moving in the country;
- VI. increase in the number of posts in the Central Drugs Standards Control Organization (CDSCO);
- VII. re-equipping of drug testing laboratories with state-of-art equipment;
- VIII. large scale nation-wide survey to determine the 'not of standard quality' drugs;
- IX. conducting workshops and training programmes for skill enhancement in areas such as Good Manufacturing Practices (GMP), Good Laboratory Practices (GLP), Good Distribution Practices (GDP), Good Clinical Practices (GCP) and Good Storage and Distribution Practices (GSP) to regulators and industry in partnership with other Departments, industry and regulators of other countries including USA and European Union.
- X. Conducting training programmes for laboratory personnel of State and Central laboratories to upgrade their analytical capabilities and skill sets.
- XI. risk based inspections of manufacturing facilities.

**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 suspended -378 Drug Lice. Cancelled-179 Court case launed - 27 FIR got registered -9
	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 calculated	7	License suspended 3 and canceled 1
Total		72712	3028	118	237	44	86	424.67 lacs	14567	-----



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 lacs 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 until further order for 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 Spurious + 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 Cancelled-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/p rosecution 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 laksh 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
<b>Total</b>		<b>74,586</b>	<b>3703</b>	<b>234</b>	<b>289</b>	<b>2</b>	<b>59</b>	<b>55313470.5 + Govt. Supply</b>	<b>3648</b>	-

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

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

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

XII.

**Number of samples tested and enforcement actions taken by State Drugs Controller during  
1st April 2016 to 30th September 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	1320	17	Nil	Nil	Nil	Nil	10470763	Nil	Nil
2	Arunachal Pradesh	65	19	4 ( Spurious 3 + misbranded 1 )	Nil	Does not arise	Does not arise	NA	NA	NA
3	Assam	295	8	Nil	Nil	Nil	Nil	Nil	Nil	Nil
4	Bihar	397	11	Nil	Nil	6	16	26311817	78	47
5	Goa	260	10	Nil	Nil	Nil	Nil	Nil	Nil	Nil
6	Gujarat	4768	208	5	16	Nil	Nil	Nil	2	under investigation
7	Haryana	1217	8	2	1	0	0	25583.12	4193	335
8	Himachal Pradesh	515	18	5	Nil	Nil	Nil	Nil	-	Nil
9	Jammu & Kashmir	1121	23	Nil	Nil	Nil	Nil	Nil	Nil	Nil
10	Karnataka	3744	219	Nil	Nil	Nil	Nil	97,937	-	-
11	Kerala	3633	66	Nil	Nil	Nil	Nil	Nil	Nil	Nil
12	Madhya Pradesh	Data not received								
13	Maharashtra	Data not received								
14	Manipur	19	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil
15	Meghalaya	97	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil
16	Mizoram	41	4	Nil	Nil	Nil	Nil	Nil	Nil	Nil
17	Nagaland	32	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil
18	Orissa	1651	54	Nil	Nil	Nil	Nil	Nil	368	No spurious/adulterated drugs detected during raid, Hence no seizure made
19	Punjab	1233	28	11	6	Nil	Nil	16,99,200	1133	10
20	Rajasthan	1054	62	9	3	0	0	199428.00	11	53
21	Sikkim	60	3	Nil	Nil	Nil	Nil	Nil	Nil	Nil
22	Tamilnadu	4691	235	1	5	Nil	Nil	Nil	207 raids have been conducted during the said period against the sales premises	252 sanction orders have been issued for launching prosecutions before the concerned court.
23	Tripura	477	3	Nil	Nil	NA	Nil	Nil	Nil	Nil

24	Uttar Pradesh	3104	423 (Sub-std.-113+ Misbranded-310)	3	70	2	41	5302948/-	730	FIR-43, persons arrested-41, Total seizure Rs. 5302948/-
25	West Bengal	399	20	Nil	Nil	Nil	Nil	Nil	Nil	Nil
26	Pondicherry	11	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil
27	Andaman & Nicobar	Nil	Nil	Nil	Nil	Nil	Nil	Nil	10	Nil
28	Chandigarh	56	1	Nil	Nil	Nil	Nil	Price of four portions seized on form 17 Rs. 622/-; drugs declared as not of standard quality	13	under investigation
29	Delhi	60	6	Nil	2	Nil	Nil	15000	17	44 firms were found contravening various provisions of D&C Rules, 1945. Action against erring firms has been initiated as per Rules.
30	Dadra & Nagar Haveli	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil
31	Daman & Diu	Data not received								
32	Lakshadweep	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil
33	Chattisgarh	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil
34	Jharkhand	108	2	Nil	1	Nil	-	-	32	Suspension-20, Prosecution-01, Cancellation-02 & FIR 09
35	Uttarakhand	203	20	Nil	Nil	Nil	Nil	Nil	Nil	Nil
36	Telangana	1378	19	Nil	Nil	Nil	Nil	Nil	Nil	Nil
<b>Total</b>		<b>32,009</b>	<b>1487</b>	<b>40</b>	<b>104</b>	<b>8</b>	<b>57</b>	<b>4,41,23,298.12</b>	<b>6794</b>	<b>-</b>

