

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

**LOK SABHA  
UNSTARRED QUESTION NO.2262  
TO BE ANSWERED ON 11<sup>TH</sup> DECEMBER, 2015**

**SPURIOUS, SUB-STANDARD AND EXPIRED DRUGS**

**2262. SHRI BHARATHI MOHAN R.K.:  
SHRI JYOTIRADITYA M. SCINDIA:  
SHRI RABINDRA KUMAR JENA:  
SHRI ALOK SANJAR:  
SHRI C. MAHENDRAN:**

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

- (a) the extent of circulation of spurious, sub-standard and expired drugs in the market, State/UT-wise;
- (b) the number of cases of spurious, sub-standard and repackaged expired drugs and related casualties reported/investigated, raids conducted and the action taken against the offenders including the erring hospitals/ dispensaries during each of the last three years and the current year, State/UT-wise;
- (c) the measures taken/proposed to be taken by the Government to strengthen the drug regulatory and monitoring mechanism in order to check the marketing and manufacturing of spurious/sub standard/ expired drugs in the country;
- (d) whether a number of States/UTs do not have drug testing laboratories, if so, the details thereof and the reasons therefor indicating the manner in which drug samples are tested there; and
- (e) whether the Government proposes to revamp the drug testing and regulatory apparatus by setting up of new drug testing laboratories in every State/UT, if so, the details thereof along with the estimated cost thereof?

**ANSWER  
THE MINISTER OF HEALTH AND FAMILY WELFARE  
(SHRI JAGAT PRAKASH NADDA)**

- (a) & (b): The details compiled by Central Drugs Standard Control Organization on the basis of information received from States/Union Territories are at Annexure I and II.
- (c): A series of measures have been taken to strengthen the Central and State drug regulatory infrastructure. These include:
  - (i.) development of an IT-enabled system for online submission of Clinical Trial applications;
  - (ii.) increase in the number of sanctioned posts in Central Drugs Standard Control Organisation (CDSCO);

- (iii.) development of e-Governance module for CDSCO;
- (iv.) re-equipping the drug testing laboratories with State of the art equipment; and,
- (v.) large scale nation-wide survey to determine 'not of standard quality' and spurious drugs.

(d): At present, States of Sikkim, Assam, Nagaland, Manipur, Mizoram and Arunachal Pradesh and Union Territories of Andaman and Nicobar, Lakswadeep, Dadra & Nagar Haveli and Daman & Diu do not have a drug testing laboratory. Drug samples drawn by inspectorate staff of these States / Union Territories are forwarded to Regional Drug Testing Laboratories (Guwahati/Chandigarh), Central Drug Testing Laboratories (Mumbai/Chennai/Hyderabad) or Central Drug Laboratories (Kolkata/Kasauli) under the Central Government for testing.

(e): In order to further strengthen the drug regulatory system in the country both at the Central and State levels, an outlay of Rs.1750 Crore has been sanctioned by the Central Government. One of the major components of this scheme is augmentation of testing capacities of laboratories both in the Centre and States / Union Territories, as well as establishment of new laboratories.

**Number of samples tested and enforcement actions taken by State Drugs Controller during 2012-13**

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
1	Andhra Pradesh	6127	78	10	2	4	-
2	Arunachal Pradesh	103	6	Nil	Nil	Nil	Nil
3	Assam	665	50	Nil	Nil	Nil	Nil
4	Bihar	<b>Data awaited</b>					
5	Goa	637	36	Nil	Nil	Nil	Nil
6	Gujarat	6907	551	4	1	1	Nil
7	Haryana	3713	52	25	1	Nil	Nil
8	Himachal Pradesh	1318	27	Nil	1	Nil	Nil
9	Jammu & Kashmir	2410	86	3	3	-	-
10	Karnataka	6336	229	2	2	Nil	3
11	Kerala	4569	189	Nil	Nil	Nil	Nil
12	Madhya Pradesh	2049	74	Nil	Nil	Nil	-
13	Maharashtra	7538	360	3	Nil	Nil	26
14	Manipur	Nil	Nil	Nil	Nil	Nil	Nil
15	Meghalaya	1	4	Nil	initiated	Nil	Nil
16	Mizoram	64	Nil	Nil	Nil	Nil	Nil
17	Nagaland	84	4	-	Nil	Nil	-
18	Orissa	4005	37	1	Instructed to file prosecution in spurious drugs cases	Nil	Nil
19	Punjab	3087	37	Nil	Nil	Nil	-
20	Rajasthan	1625	81	15	36	Nil	2
21	Sikkim	47	Nil	Nil	Nil	Nil	Nil
22	Tamil Nadu	3906	210	4	9	1	Nil
23	Tripura	236	Nil	Nil	Nil	Nil	Nil
24	Uttar Pradesh	1016	161	3	156	Nil	76
25	West Bengal	1186	35	Nil	2	Nil	3
26	Pondicherry	Nil	Nil	Nil	Nil	Nil	Nil
27	Andaman & Nicobar Island	1	Nil	Nil	Nil	Nil	Nil
28	Chandigarh	109	8	Nil	Nil	Nil	Nil
29	Delhi	475	19	Nil	Nil	Nil	Nil
30	Dadra & Nagar Haveli	Nil	Nil	Nil	Nil	Nil	Nil
31	Daman & Diu	58	Nil	Nil	Nil	Nil	Nil
32	Lakshadweep	Nil	Nil	Nil	Nil	Nil	Nil
33	Chattisgarh	15	4	Nil	Nil	Nil	Nil
34	Jharkhand	38	11	Nil	Nil	Nil	Nil
35	Uttaranchal	212	13	Nil	1	Nil	Nil
	<b>Total</b>	<b>58537</b>	<b>2362</b>	<b>70</b>	<b>214</b>	<b>6</b>	<b>110</b>

**Number of samples tested and enforcement actions taken by State Drugs Controller during  
2013-14**

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
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
<b>Total</b>		<b>72712</b>	<b>3028</b>	<b>118</b>	<b>237</b>	<b>44</b>	<b>86</b>	<b>424.67 lacs</b>	<b>14567</b>	<b>-----</b>





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 violation 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 April to September, 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	1196	8	Nil	Nil	Nil	Nil	Nil	Nil	Nil
2	Arunachal Pradesh	12	3	Nil	Nil	Nil	Nil	Nil	Nil	Nil
3	Assam	157	3	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	233	4	Nil	Nil	Nil	Nil	Nil	Nil	Nil
6	Gujarat	3342	183	1	23	Nil	Nil	Nil	11	under investigation
7	Haryana	734	26	Nil	1	Nil	Nil	Nil	5622	223 cancelled 24 suspended
8	Himachal Pradesh	555	13	Nil	Nil	Nil	Nil	Nil	Nil	Nil
9	Jammu & Kashmir (*)	703	19	1	Nil	Nil	Nil	1,042,468	Nil	Nil
10	Karnataka	3121	194	Nil	Nil	Nil	Nil	1283160/-	Nil	Nil
11	Kerala	2759	82	Nil	Nil	Nil	Nil	Nil	Nil	Nil
12	Madhya Pradesh	928	19	Nil	Nil	Nil	Nil	Nil	Nil	Nil
13	Maharashtra	2507	194	17	17	investigation in process	5	994437	4	FIR Launched
14	Manipur	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil
15	Meghalaya	41	12	Nil	Nil	Nil	Nil	Nil	Nil	Nil
16	Mizoram	48	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil
17	Nagaland	26	Result awaited	Nil	Nil	Nil	Nil	Nil	Nil	Nil
18	Orissa	1941	35	Nil	Nil	Nil	Nil	Nil	427	No. of seized made-14
19	Punjab	1626	73	43	Action under process, prosecution bound to be launched	Nil	2	2146022	318	casess are under investigation
20	Rajasthan	1032	79	3	13	-	-	2026.5	-	-
21	Sikkim	41	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil
22	Tamilnadu	4735	263	2	1*	Nil	Nil	Rs. 25000	190	casess are under investigation
23	Tripura	315	19	Nil	Nil	NA	Nil	Nil	Nil	Nil
24	Uttar Pradesh	3497	313	32	33	Nil	38	4034486/-	655	FIR-44 Person arrested-38

25	West Bengal	337	7	Nil	Nil	Nil	Nil	Nil	Nil	Nil
26	Pondicherry	8	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil
27	Andaman & Nicobar	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil
28	Chandigarh	66	1	None	None	None	None	Rs- 5599/- of samples drugs and Rs- 173770/- approx. Of drugs seized vide form-16	5	1 prosecution launched against the firm in the Hon'ble court and remaining 3 under investigation
29	Delhi	89	9	Nil	1	Nil	Nil	Rs-4 lakh were seized from unlicensed premises	5*	22 firms were found contravening various provision of D & C Rules 1945. Action against them under process
30	Dadra & Nagar Haveli	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil
31	Daman & Diu	7	Nil	Nil	NA	2	Nil	Nil	Nil	NA
32	Lakshadweep	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil
33	Chattisgarh	24	6	Nil	1	Nil	1	2612268/-	2	Nil
34	Jharkhand	319	21	Nil	Nil	Nil	Nil	Nil	53	FIR-11 Suspension-29 Cancelled -2
35	Uttarakhand	91	11	Nil	Nil	Nil	Nil	Nil	Nil	Nil
36	Telangana	2620	12	Nil	Nil	Nil	Nil	720000/-	1	Seized 500kgs spurious drugs Lactic acid bacillus the case under investigation, complaint will be filled in the Hon'ble court after completion of investigation
<b>Total</b>		<b>33,464</b>	<b>1612</b>	<b>99</b>	<b>89</b>	<b>2</b>	<b>49</b>	<b>12,791,237</b>	<b>7321</b>	<b>-</b>

Note: The numbers given in column 6 indicates the cases detected earlier.

Note: (\*) indicates that the data is available from April to June, 2015.





**Statement Showing case of expired drugs, Quantity expired drugs seized, No. of person arrested, approximate value of drugs seized, Action taken against offenders, No. of Prosecution launched for expired drug and No. of cases (as mentioned in the earlier column) decided during 2013-14 as per the feed back available from the States.**

S.No.	States	Cases of expired drugs	Quantity expired drugs seized	No. of person arrested	Approximate value of drugs seized (in Rs)	Action taken against offenders	No. of Prosecution launched for expired drug	No. of cases (as mentioned in the earlier column)
1	Andhra Pradesh	Nil	Nil	N/A	Nil	N/A	Nil	N/A
2	Arunachal Pradesh	Nil	Nil	Nil	Nil	Nil	Nil	Nil
3	Assam	Nil	Nil	Nil	Nil	Nil	Nil	Nil
4	Bihar *	Nil	Nil	Nil	Nil	Nil	Nil	Nil
5	Goa	Nil	Nil	Nil	Nil	Nil	Nil	Nil
6	Gujarat	Nil	Nil	Nil	Nil	Nil	Nil	Nil
7	Haryana	Nil	Nil	Nil	Nil	Nil	Nil	Nil
8	Himachal Pradesh	Nil	Nil	Nil	Nil	Nil	Nil	Nil
9	Jammu & Kashmir	1 Inj. Neogest Exp Dt: Aug 2013, sold on 27.01.2014 by M/s Kidney Medicate Sonawar, Sringar	15 Ampoules or various drugs other than Neogest	Nil (case Subjudice)	Rs. 4278	Prosecution launched against M/s Kidney medicate Sonawar, Srinagar	1	Nil
10	Karnataka	1	Nil	Nil	24	The licenseng Authority, Hassan Circle cancelled the license in Forms 20 & 21 of M/s Mallikarjun Medicals, Belur Hassan District	Nil	M/s Mallikarjun Medicals, Belur, Hassan District preferred appeal before the Principal Secretary , Health and Family Welfare Department, Gpovernment of Karnataka the Appellate Authority under the provisions of Drugs and Cosmetics Rules 194. the Appellate Authority upheld the order passed



33	Chattisgarh	Nil	Nil	Nil	Nil	Nil	Nil	Nil
34	Jharkhand	1	Nil	Nil	Rs. 700	Under Process	F.I.R.-01	Not reported
35	Uttarakhand	1 (sale of 5 tabets of expired Voveron)	On raid further stock of expired drugs not found hence no seizure	Nil	Nil	On the basis of complaint with cash memo and the licensee accepted as unintentional mistake, hence license suspended for 15 days	Nil	
36	Telangana	Nil	Nil	Nil	Nil	Nil	Nil	Nil

(\* ) Data received till September, 2013

**Statement Showing case of expired drugs, Quantity expired drugs seized, No. of person arrested, approximate value of drugs seized, Action taken against offenders, No. of Prosecution launched for expired drug and No. of cases (as mentioned in the earlier column) decided during 2014-15 as per the feed back available from the States.**

S.No.	States	Cases of expired drugs	Quantity expired drugs seized	No. of person arrested	Approximate value of drugs seized (in Rs)	Action taken against offenders	No. of Prosecution launched for expired drug	No. of cases (as mentioned in the earlier column)
1	Andhra Pradesh	1	20 varieties of drugs	...	20,000	U.I	....	....
2	Arunachal Pradesh	Nil	Nil	Nil	does not arise	Does not arise	Nil	Nil
3	Assam	Nil	Nil	Nil	Nil	Nil	Nil	Nil
4	Bihar *	1	557 units	5	40,000	FIR-2	Under Process	2
5	Goa	Nil	Nil	Nil	Nil	Does not arise	Nil	Nil
6	Gujarat	Nil	Nil	Nil	Nil	Nil	Nil	Nil
7	Haryana	Nil	Nil	Nil	Nil	Nil	Nil	Nil
8	Himachal Pradesh	Nil	NA	Nil	NA	NA	Nil	NA
9	Jammu & Kashmir	Inj. Neogest. Exp dt: Aug 2013, sold on 27.01.2014 by M/s Kidney Medicate, Sonawar, Srinagar	15 Ampoules of various drugs other than Neogest	Nil (Summon issued & offenders presented themselves before the Hon'ble Court)	4278	Prosecution launched against M/s Kidney Medicate, Sonwar	1	Nil
10	Karnataka	2	....	....	....	....	2	2
11	Kerala	Nil	Nil	Nil	Nil	Nil	Nil	Nil
12	Madhya Pradesh	Nil	Nil	Nil	Nil	Nil	Nil	Nil
13	Maharashtra	Nil	NA	NA	NA	NA	NA	NA
14	Manipur	Nil	Nil	Nil	Nil	Nil	Nil	NA
15	Meghalaya	Nil	Does not arise	Does not arise	Does not arise	Does not arise	Does not arise	Does not arise
16	Mizoram	Nil	Nil	Nil	Nil	Nil	Nil	Nil
17	Nagaland	Nil	Nil	Nil	Nil	Nil	Nil	Nil
18	Orissa	Nil	Nil	Nil	Nil	Nil	Nil	Nil
19	Punjab	5	Data Not Available at HQ	Nil	73,264	action under process	1	Nil
20	Rajasthan	0	0	0	0	0	0	0
21	Sikkim	Nil	Nil	Nil	Nil	Nil	Nil	Nil
22	Tamil Nadu	Nil	NA	Nil	Nil	prosecutions launched before the concerned court in 10 cases. All the 10 cases are under trial before the Hon'ble court.	10	Nil
23	Tripura	10	Nil	Nil	0	Action has been initiated	Nil	Nil



24	Uttar Pradesh *	1	309x 10 Tablets of various brands 38x10 Capsules of various brands 14x5ml LVP & 5x40 Condoms	1	15000	FIR lodged, person arrested	1	Nil
25	West Bangal	Nil	NA	NA	NA	NA	NA	NA
26	Pondicherry	Nil	Nil	Nil	Nil	Nil	Nil	Nil
27	Andaman & Nicobar Island	Nil	Nil	Nil	Nil	Nil	Nil	Nil
28	Chandigarh	None	None	None	None	None	None	None
29	Delhi	2	Nil	Nil	Nil	Licence Suspended	Nil	Nil
30	Dadra & Nagar Haveli	Nil	Nil	Nil	Nil	Nil	Nil	Nil
31	Daman & Diu *	Nil	NA	Nil	NA	Nil	NA	NA
32	Lakshadweep	Nil	Nil	Nil	Nil	Nil	Nil	Nil
33	Chattisgarh	1	5 cartoon	Nil	30000	Nil	Nil	Nil
34	Jharkhand	2	1 box & 523 tab	Nil	Nil	Nil	1	Nil
35	Uttarakhand	Nil	Nil	Nil	Nil	Nil	Nil	Nil
36	Telangana	Nil	Nil	Nil	Nil	Nil	Nil	Nil

(\* ) Data received till September, 2014.



24	Uttar Pradesh	2	about 76 gunny bages expired medicines	1	5 lakh	FIR Lodged , person arristed	Nil	Nil
25	West Bangal	Nil	Nil	Nil	Nil	Nil	Nil	Nil
26	Pondicherry	Nil	Nil	Nil	Nil	Nil	Nil	Nil
27	Andaman & Nicobar Island	Nil	Nil	Nil	Nil	Nil	Nil	Nil
28	Chandigarh	1	20 capsules and 1 ointment	None	Rs 472 approx.	Show cause notice was issued to the firm	None	None
29	Delhi	Nil	Nil	Nil	Nil	Nil	Nil	Nil
30	Dadra & Nagar Haveli	Nil	Nil	Nil	Nil	Nil	Nil	Nil
31	Daman & Diu	Nil	Nil	Nil	Nil	Nil	Nil	Nil
32	Lakshadweep	Nil	Nil	Nil	Nil	Nil	Nil	Nil
33	Chhattisgarh	1	Nil	Nil	58,784/-	Under court trial	Nil	Nil
34	Jharkhand	3	-	-	Rs 2000 Approx	02- Suspension	-	-
35	Uttarakhand	Nil	Nil	Nil	Nil	Nil	Nil	Nil
36	Telangana	Nil	Nil	Nil	Nil	Nil	Nil	Nil
<b>Total</b>		<b>28</b>	<b>-</b>	<b>6</b>	<b>5872624</b>	<b>Nil</b>	<b>3</b>	<b>Nil</b>

Note: The numbers given in column 8 indicate the cases detected earlier.

Note: (\*) indicates that the data is available from April, 2015 to June, 2015.