

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

**LOK SABHA
UNSTARRED QUESTION NO. 1262
TO BE ANSWERED ON 22ND DECEMBER, 2017**

SPURIOUS AND SUBSTANDARD DRUGS

1262. SHRI AJAY MISRA TENI:

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

- (a) whether sale and marketing of spurious, substandard and expired drugs including ayurvedic/homoeopathic drugs and deaths therefrom have been reported in the country;
- (b) if so, the details thereof indicating the value of drugs and the action taken against the offenders during each of the last three years and the current year, State/UTwise;
- (c) whether the Government has any proposal under consideration for entering into international cooperation and a global treaty to deal with the menace of spurious and substandard drugs reaching the market;
- (d) if so, the details thereof; and
- (e) the other measures being taken by the Government to effectively deal with the menace of spurious, substandard and expired drugs?

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

(a) & (b): The Government has not received any report regarding deaths due to spurious, substandard and expired drugs.

The manufacture, sale and distribution of drugs in the country are 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 action against violation of any provision of the Act and Rules. As per information received from State/UTs, the details regarding the number of drug samples tested, number of drug samples reported spurious/adulterated and sub-standard, value of drugs seized and action taken by States/UTs are enclosed as **Annexure-I**. Such data in respect of expired drugs is at **Annexure-II**.

(c): No.

(d): Does not arise.

(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 including strengthening legal provisions, workshops and training programmes for manufacturers and regulatory officials and measures such as risk based inspections.

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/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

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)

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

ANNEXURE - II

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 coloumn) 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 coloumn)
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 til September 2014

22	Tamil Nadu	6	75 items of varying quantity	Nil	Rs. 2000000/-	Prosecutions launched before the concerned court in three cases. All the 3 cases are under tiral before the Hon'ble court	3 (The cses detected before the 01.04.2015)	Nil
23	Tripura	1	91 items	Nil	Not Calculated	Under Process	Nil	Nil
24	Uttar Pradesh	2	About 76 Gunny bages of expired medicine	1	5 lakhs	FIR lodged, person arrested	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	Nil	Nil	Nil	Nil	Nil	Nil	Nil
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	1 items	Nil	25000	prosecution launched	1	Nil
34	Jharkhand	5	-	-	Approximate 4000	04 Suspension	-	-
35	Uttarakhand	-	-	-	-	-	-	-
36	Telangana	330	variety of drugs seized	Nil	1,17,800/-	329	1	-
Total		362	272	4	94944.54	339	15	-
(*) = Data as on April 2015 to Feb 2016								
(**) = Data as on 1st April to 30 th sept. 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 coloumn) decided during 1st April 2016 to 31st March 2017 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 coloumn)
1	Andhra Pradesh	Nil	Nil	Nil	Nil	Nil	Nil	Nil
2	Arunachal Pradesh	Nil	Nil	Nil	Nil	Nil	Nil	Nil
3	Assam	Nil	Nil	Nil	Nil	Nil	Nil	Nil
4	Bihar*	4	51	6	819034	Data not received	Nil	Nil
5	Goa	Nil	Nil	Nil	Nil	Nil	Nil	Nil
6	Gujarat	2	Nil	Nil	Nil	Nil	2	under Investigation
7	Haryana	Nil	Nil	Nil	Nil	Nil	Nil	Nil
8	Himachal Pradesh	1	Small Quantity (Out of drugs seized from a chemist for physician samples etc., few strips of expired drugs were also seized)	Nil	Rs. 1000 approx.	A case has been registered against the accused under the Drugs and Cosmetics Act and is under investigation.	Nil	Nil
9	Jammu & Kashmir	1	5 vials of Megapen & 3 vials of Walamicin	Nil	174	Prosecution Launched	1	Nil
10	Karnataka	Nil	Nil	Nil	Nil	Nil	Nil	Nil
11	Kerala	Nil	Nil	Nil	Nil	Nil	Nil	Nil
12	Madhya Pradesh	Nil	Nil	Nil	Nil	Nil	Nil	Nil
13	Maharashtra	Nil	Nil	Nil	Nil	Nil	Nil	Nil
14	Manipur*	Nil	Nil	Nil	Nil	Nil	Nil	Nil
15	Meghalaya*	Nil	Nil	Nil	Nil	Nil	Nil	Nil
16	Mizoram	Nil	Nil	Nil	Nil	Nil	Nil	Nil
17	Nagaland	Nil	Nil	Nil	Nil	Nil	Nil	Nil
18	Orissa	2	20 items of drugs	Nil	15795	(i) Case registered 2(c)cc-424/16 in court of Hon'ble SDJM, Berhampur (ii) Case registered 2(c)cc 423/16 in court of Hon'ble SDJM, Berhampur	2	Sub Judge

19	Punjab	7	5904 items of drugs	Nil	1,15,605	Licences of 6 chemists have suspended	Nil	Licences of 6 chemists have suspended
20	Rajasthan	Nil	Nil	Nil	Nil	Nil	Nil	Nil
21	Sikkim	Nil	Nil	Nil	Nil	Nil	Nil	Nil
22	Tamil Nadu	2	82 items of drugs	Nil	Rs.8147/-	Prosecutions launched before the concerned court in two cases. All the 4 cases are under trial before the Hon'ble court.	4#	Nil
23	Tripura	1	398 bottles	Nil	35933	Licenses cancelled	Nil	Nil
24	Uttar Pradesh	Nil	Nil	Nil	Nil	Nil	Nil	Nil
25	West Bangal	1	Nil	2	Rs. 10 Lakhs	Prosecutions launched	1	Nil
26	Pondicherry	Nil	Nil	Nil	Nil	Nil	Nil	Nil
27	Andaman & Nicobar Island*	Nil	Nil	Nil	Nil	Nil	Nil	Nil
28	Chandigarh	Nil	Nil	Nil	Nil	Nil	Nil	Nil
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	Nil	Nil	Nil	Nil	Nil	Nil	Nil
34	Jharkhand	Nil	Nil	Nil	Nil	Nil	Nil	Nil
35	Uttarakhand	Nil	Nil	Nil	Nil	Nil	Nil	Nil
36	Telangana	Nil	Nil	Nil	Nil	Nil	Nil	Nil
Total		21		8	1995688		10	
(*) = Data as on April 2016 to September 2016								
# = indicate the case detected before the mentioned period								