

**GOVERNMENT OF INDIA
MINISTRY OF AYURVEDA, YOGA & NATUROPATHY,
UNANI, SIDDHA AND HOMOEOPATHY
(AYUSH)**

**LOK SABHA
UNSTARRED QUESTION NO. 3212
TO BE ANSWERED ON 12TH JULY, 2019**

SPURIOUS PHARMACIES

3212. SHRI A. RAJA:

Will the Minister of **AYURVEDA, YOGA AND NATUROPATHY, UNANI, SIDDHA AND HOMOEOPATHY (AYUSH)** be pleased to state:

- (a) whether the cases of low quality medicines being marketed by spurious pharmacies have come to the knowledge of the Government during the last three years and the current year, State/UT-wise;
- (b) the action taken/being taken by the Government in this regard; and
- (c) whether the Government is planning to develop any mechanism to check such spurious pharmacies and, if so, the details thereof?

**ANSWER
THE MINISTER OF STATE (IC) OF THE MINISTRY OF AYURVEDA,
YOGA & NATUROPATHY, UNANI, SIDDHA AND HOMOEOPATHY
(SHRI SHRIPAD YESSO NAIK)**

(a) & (b): The manufacturing for sale and distribution of medicines is primarily regulated in the country under the provisions of Drugs & Cosmetics Act, 1940 & Rules 1945 made thereunder. For this purpose a system of licensing and inspection of drug manufacturing units by the Drug Regulatory Authorities appointed by the respective State Governments is in place for quality control of medicines. Every licensed drug manufacturing unit is required to comply with all the conditions of license as prescribed under Drugs & Cosmetics Rules, 1945. Since the enforcement of legal provisions for medicines as prescribed in the Drugs & Cosmetics Act, 1940 and Rules thereunder is vested with the State Governments, the State Licensing Authorities are empowered to take action on violation of any of the conditions of such licenses including monitory punishment and prosecution in appropriate Court of Law. Statement of state-wise reported cases of spurious or substandard Ayurvedic, Siddha, Unani and Homoeopathy medicines during the last four years is provided in the **Annexure**.

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(c): The mechanism of checking spurious pharmacies is prescribed in the Drugs & Cosmetics Act and Rules. Central Government has taken following regulatory measures to ensure effective quality control of medicines in the country-

- i) The Drugs and Cosmetics Act, 1940 has been amended to provide stringent penalties for manufacture of spurious and adulterated drugs including provision for certain cognizable and non-bailable offences.
- ii) Guidelines for taking action on samples of drugs declared spurious or not of standard quality in the light of enhanced penalties under the Drugs & Cosmetics (Amendment) Act, 2008 have been circulated to the State Drug Controllers for uniform implementation.
- iii) States / UTs were requested to set up special Courts for trial of offences under the Drugs and Cosmetics Act for speedy disposal. 28 States are reported to have set up designated special Courts for trial of cases of spurious and sub-standard drugs.
- iv) Number of regulatory posts has been increased and strengthening of State enforcement framework, pharmacies and drug testing laboratories supported to improve the capacity for quality control of medicines.
- v) Drugs & Cosmetics Rules, 1945 have been amended in respect of seeking compliance to various license requirements for manufacturing of medicines.

ANNEXURE**State/UT wise number of ASU&H medicines tested and declared spurious or sub-standard in the last four years**

State/UT	Samples tested by Drug Testing Laboratory							
	2015-16		2016-17		2017-18		2018-19	
	Tested	Failed/Sub Standard	Tested	Failed/Sub standard	Tested	Failed/Sub standard	Tested	Failed/Sub standard
Arunachal Pradesh	-	-	91 A&H	NA	145	NA	80	NA
Assam	319 A	4	146 A	-	115A	-	106A	-
Chandigarh	-	-	715 A, 48U	-	423A, 9 U	-	-	-
Chhattisgarh			75 A	--	149A	6	69A	1
Delhi	3000 A, 1000 U	13 A, 7 U	2048 A, 100U	11 A, 11U	600 A, 200U	4A, 1U		
Goa	-	-	10	-	1	-	-	-
Gujarat	322A, 5H	10	267 ASU, 58H	NA	298 ASU, 4H	NA	110 ASU	NA
Himachal Pradesh	-	-	748 ASU	53	577 ASU	61	94 ASU	4
Jharkhand	-	-	-	-	33H	3	-	-
Karnataka	-	-	1071 A, 87H	-	1026A, 30H	-	-	-
Kerala	297A	7	297A	5	578	25	724	9
Maharashtra	-	-	350	-	320	-	-	-
Manipur	NA	-	NA	-	NA	-	--	-
Meghalaya	15A, 10H	NA	15A, 15H	NA	11A, 9H	NA	5A, 2H	NA
Mizoram	-	-	31	11	-	-	-	-
Nagaland	-	-	NA	-	NA	-	-	-
Odisha	-	-	45	-	53	-	-	-
Puducherry	-	-	-	-	-	-	-	-
Punjab	921 A, 12U	119 A, 3 U	715A, 48U	99A, 2U	423A, 9U	55A	886A	69A
Tamilnadu	-	-	1809 ASU	128	1821	74	537	33
Tripura	15H	-	67 ASU	--	200 ASU, 1H	--	66ASU, 132H	--
Uttarakhand	111 ASU	12	187 ASU	-	250 ASU	53	27 ASU	3
West Bengal	-	-	8	-	0	-	-	-

**Abbreviations used: A: Ayurvedic, S: Siddha, U: Unani, H: Homoeopathy, NA: Information Not Available.*