

**GOVERNMENT OF INDIA
MINISTRY OF AYUSH**

**LOK SABHA
UNSTARRED QUESTION NO. 3043
TO BE ANSWERED ON 09th AUGUST 2024**

“Quality AYUSH Medicines”

3043. Shri Navaskani K:

Dr. Thirumaavalavan Tholkappiyan:

Dr. D Ravi Kumar:

Shri C N Annadurai:

Shri Selvam G:

Will the Minister of AYUSH be pleased to state:

- (a) whether the Government has taken steps to provide quality AYUSH medicines at affordable rates in the country and if so, the details thereof;
- (b) whether there is a steep increase in the prices of AYUSH medicines in recent times and if so, the details and reasons thereof and the corrective steps taken/proposed to be taken in this regard;
- (c) whether any measures to ensure availability of Ayurveda medicines through Jan Aushadhi outlets are under consideration of the Government and if so, the details thereof;
- (d) whether the Government has also taken any stringent measures to control and curb the sale of spurious Ayurvedic and Unani medicines in the country and if so, the details thereof; and
- (e) the details of the number of cases lodged against the sale and distribution of spurious medicines, State/UT-wise and year-wise during the last three years?

ANSWER

**THE MINISTER OF STATE (IC) OF THE MINISTRY OF AYUSH
(SHRI PRATAP RAO JADHAV)**

(a) and (c) Under Rule 158 B of Drugs & Cosmetics Rules, 1945, guidelines for issue of license and requirement of safety study and Experience/Evidence of effectiveness with respect to Ayurveda, Siddha or Unani drugs has been prescribed. It is mandatory for the manufacturers to adhere to the prescribed requirements for licensing of manufacturing units & medicines including proof of safety & effectiveness, compliance with the Good

Manufacturing Practices (GMP) as per Schedule T and Schedule M-I of Drugs and Cosmetics Rules, 1945 and quality standards of drugs given in the respective pharmacopoeia.

At present 5 selected Ayurvedic products have been added in the product basket of Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP), which are being made available through selected Kendras at affordable rates.

(b) No study has been conducted regarding the price of Ayush medicines.

(d) and (e) Yes sir. The Drugs & Cosmetics Act, 1940 and Rules made there under have exclusive regulatory provisions for Ayurvedic, Siddha, Unani, and Homoeopathy drugs. Provisions related to spurious Ayurveda, Siddha and Unani drugs are prescribed under Section 33EEA and penalty for manufacture for sale or for distribution of any such drugs are prescribed under section 33 I of Drugs and Cosmetics Act, 1940. Further, Rule 159 of Drugs and Cosmetics Rules, 1945 have provisions for cancellation or suspension of licences if the licensee has failed to comply with any of the conditions of the licence or with any provisions of the Drugs and Cosmetics Act, 1940 or the rules made thereunder.

As prescribed in Drugs and Cosmetics Act 1940 and Rules 1945 made thereunder, enforcement of the legal provisions pertaining to Quality Control and issuance of drug license of Ayurveda, Siddha and Unani drugs, is vested with the State Drug Controllers/State Licensing Authorities appointed by the concerned State/ Union Territory Government.

As per the information received from States/ UTs governments, details of the number of cases lodged against the sale and distribution of spurious medicines, State/UT-wise and year-wise during the last three are as follows:

S.no.	Name of the State/ UT	Details																							
1.	Gujarat	2021- NIL																							
		2022																							
		S.No	Product	Mfg. Name	Reason	Action taken																			
		1	TulsiSantraAshv a herbal tonic	Tulshi Ayurveda, Rajkot	The sample contains 13.38 percent v/v ethyl alcohol/Sp urious	Court case launched court case no. 2054/2022 , Dated- 09/12/202 2																			
		2	Prashovan Tablets	Relabeling PareshHari lalChovati ya	Relabeling /Spurious	Court case launched court case no. 21356/202 2, Dated- 01/09/202 2																			
		2023																							
3	New Orthonil Powder	Babaji Herbals Punjab	Presence of prednisolo ne in Ayurvedic product	Court case launched court case no. 22173/202 3, Dated- 28/08/202 3																					
2024- NIL																									
2.	Tamil Nadu	<ul style="list-style-type: none"> No cases booked for last three years. However the product suspension/cancellation against the sale and distribution of spurious medicines were taken for last three years. 																							
3.	Maharashtra	<table border="1"> <thead> <tr> <th>Period</th> <th>No. of samples</th> <th colspan="2">Action</th> </tr> </thead> <tbody> <tr> <td>2021</td> <td>17</td> <td colspan="2">Issued consent letter for prosecution.</td> </tr> <tr> <td>2022</td> <td>23</td> <td colspan="2">Issued consent letter for prosecution.</td> </tr> <tr> <td>2023</td> <td>02</td> <td colspan="2">Issued consent letter for prosecution.</td> </tr> <tr> <td>2024</td> <td>12</td> <td colspan="2">Issued consent letter for prosecution.</td> </tr> </tbody> </table>				Period	No. of samples	Action		2021	17	Issued consent letter for prosecution.		2022	23	Issued consent letter for prosecution.		2023	02	Issued consent letter for prosecution.		2024	12	Issued consent letter for prosecution.	
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4.	Jharkhand	Date	Drug	Manufacturing firm	Status																				
		28-09-2022	REPL	Renovision Export	Persecution																				

			Orthovit Capsule	Pvt Ltd Unit II, Karnidih, Chilgu, Chandil, Kharsawan- 832401.	filed. P.O. PS:
5.	Goa	<ul style="list-style-type: none"> No such cases has been launched for sale and distribution of spurious Ayurvedic medicines for sale 3 years by this Directorate. 			
6.	Mizoram	<ul style="list-style-type: none"> Mizoram does not have any cases booked against the sale and distribution of spurious Ayush medicines. 			
7.	Odisha	<ul style="list-style-type: none"> No such cases of spurious drugs have come to notice during the last three years. 			
8.	J&K	<ul style="list-style-type: none"> In the UT of J&K the monitoring of Ayush companies for selling any spurious Ayurveda and Unani drugs in being looks after by Drug and Food Control Organization J&K. 			
9.	Andhra Pradesh	<ul style="list-style-type: none"> Notices have been issued. 			
10.	Andaman Nicobar	<ul style="list-style-type: none"> No such case of sale and distribution of spurious medicines have been reported to the UT Administration during last three years. 			
11.	Manipur	<ul style="list-style-type: none"> No such cases found in the state. 			
12.	Karnataka	<ul style="list-style-type: none"> No such cases reported in the state of Karnataka. 			
13.	Madhya Pradesh	<ul style="list-style-type: none"> No complaint received regarding spurious medicines. 			
14.	Himachal Pradesh	NIL Information.			
15.	Delhi	NIL Information.			
16.	Chhattisgarh	NIL Information.			
17.	Uttar Pradesh	NIL Information.			
18.	Ladakh	NIL Information.			
19.	Puducherry	NIL Information.			
20.	Arunachal Pradesh	NIL Information			
21.	Lakshadweep	NIL Information			
22.	Tripura	NIL Information			
