

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

**RAJYA SABHA  
STARRED QUESTION NO. 65  
TO BE ANSWERED ON 13<sup>TH</sup> DECEMBER, 2022**

**UNREGULATED AND UNCERTIFIED AYURVEDIC MEDICINES**

**65. SHRI DEREK O' BRIEN:**

Will the Minister of AYUSH be pleased to state:

- (a) the number of Ayurvedic medicines in circulation which do not comply with the Drugs and Cosmetics Act, 1940; and
- (b) the number of cases of severe side effects including fatalities, due to the consumption of such uncertified medicines?

**ANSWER  
THE MINISTER OF AYURVEDA, YOGA & NATUROPATHY, UNANI,  
SIDDHA AND HOMOEOPATHY (AYUSH)  
(SHRI SARBANANDA SONOWAL)**

(a) & (b) A Statement is laid on the Table of the House.

**STATEMENT REFERRED TO IN REPLY TO RAJYA SABHA  
STARRED QUESTION NO. 65\* FOR 13<sup>TH</sup> DECEMBER, 2022**

(a) & (b) Sir, As prescribed in Drugs and Cosmetics Act 1940 and Rules 1945 made thereunder, enforcement of the legal provisions pertaining to regulation and Quality Control of Ayurveda, Siddha, and Unani drugs, is vested with the State drug Controllers/ State Licensing Authorities appointed by the concerned State Government/ Union Territory. Rule 158-B in the Drugs and Cosmetics Rules, 1945 provides the regulatory guidelines for issue of license to manufacture Ayurvedic, Siddha, Unani medicines.

As per the information received from State/UT government, the number of Ayurvedic medicines in circulation which do not comply with the Drugs and Cosmetics Act, 1940 and Rules thereunder and the number of cases of severe side effects including fatalities, due to the consumption of such uncertified medicines are as follows –

<b>S.no.</b>	<b>Name of the State/UTs</b>	<b>No. of Ayurvedic medicines which do not comply with the Drugs and Cosmetics Act, 1940 and Rules thereunder</b>	<b>No. of cases of severe side effects including fatalities</b>
1.	Andhra Pradesh	NIL	NIL
2.	Arunachal Pradesh	NIL	NIL
3.	Assam	NIL	NIL
4.	Chhattisgarh	NIL	NIL
5.	Goa	NIL	NIL
6.	Gujarat	NIL	NIL
7.	Himachal Pradesh	NIL	NIL
8.	Karnataka	NIL	NIL
9.	Kerala	17 cases were initiated against different manufacturing units from 2017 in which 113 medicines were found to be non-compliant to Drugs & Cosmetics Act, 1940. Details at <b>Annexure-I</b>	NIL
10.	Manipur	NIL	NIL
11.	Meghalaya	NIL	NIL
12.	Mizoram	Out of 278 samples tested during April-November, 2022, 04 drugs (02 Ayurvedic & 02 Homoeopathic) drugs were found to be non-compliant to Drugs and Cosmetics Act, 1940. Details at <b>Annexure-II</b>	No such cases have been reported
13.	Maharashtra	Out of 675 samples tested, 21 samples of Ayurvedic medicines were found to be non-compliant to Drugs and Cosmetics Act, 1940 during 01.04.2021 to 31.10.2022. Details at <b>Annexure-III</b>	NIL

14.	Odisha	NIL	NIL
15.	Punjab	NIL	NIL
16.	Tamil Nadu	NIL	NIL
17.	Tripura	NIL	NIL
18.	Uttar Pradesh	NIL	NIL
19.	West Bengal	NIL	NIL
20.	Andaman and Nicobar Islands	NIL	NIL
21.	Delhi	NIL	NIL
22.	Jammu and Kashmir	NIL	NIL
23.	Lakshadweep	NIL	NIL
24.	Puducherry	NIL	NIL

One Ayurvedic medicine were noticed as misbranded medicine under D & C Act, 1940 by Medicine Inspection Committee (MIC) of Central Government Health Scheme (CGHS) and Drug licensing authority of the concerned State/UT has been directed to initiate necessary action over the same.

Pharmacovigilance Program for Ayurveda, Siddha, Unani and Homoeopathy (ASU&H) Drugs set up in different parts of the country under the Central Scheme of the Ministry of Ayush are mandated to monitor and report misleading advertisements to the respective State Regulatory Authorities. This program also functions with the objective of inculcating culture of reporting suspected Adverse Drug Reactions. A three-tier structure comprising of a National Pharmacovigilance Co-ordination Centre (NPvCC), Intermediary Pharmacovigilance Centres (IPvCs) and Peripheral Pharmacovigilance Centres (PPvCs) is established and the program is functional since 2018. All India Institute of Ayurveda (AIIA), New Delhi under the Ministry of Ayush is the National Pharmacovigilance Co-ordination Centre (NPvCC) for the implementation of this program.

To generate awareness regarding the AYUSH therapeutic approaches and educate about the systematic use of AYUSH drugs, and to inculcate the reporting culture in healthcare professionals; the program organizes frequent awareness events across the country. About 554 such awareness programs were organized during these four years and about 48500 professionals have been sensitized. The details are as below:

Year	Awareness programs conducted	Beneficiaries
Jan – Dec2018	55	850
Jan – Dec2019	60	4300
Jan – Dec2020	78	8069
Jan – Dec 2021	118	14659
Jan – Nov 2022	243	20521
Total	554	48399

Under this program, Objectionable advertisements are being reported to the respective State Licensing Authorities by these centers at regular intervals. A total of 25657 such misleading advertisements have

been reported to the State Licensing Authorities by these centers. The number of such reports submitted to the state licensing authorities is as below.

Year	Number of misleading advertisements
Jan – Dec 2018	411
Jan – Dec 2019	4395
Jan – Dec 2020	6032
Jan – Dec 2021	8187
Jan – Nov 2022	6632
Total	25657

Since 2018, the center has started receiving the suspected reactions. These are the individual case safety reports and can be signals for future references. The numbers of such communications are as below-

Year	Number of individual case safety reports
Jan – Dec 2019	315
Jan – Dec 2020	282
Jan – Dec 2021	364
Jan – Nov 2022	285
Total	1246

Maximum of these reports are mild in nature. None of them were found to be serious and none required hospitalization. No fatality was noticed and all the reports were non-serious in nature.

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<b>Drugs tested as Not of Standard Quality (NSQ) that were reported from 2017</b>			
<b>Sl.No</b>	<b>Product Name</b>	<b>Manufacturing Unit</b>	<b>Action Taken</b>
1	Lanthakkuru	Santhigiri Ayurveda Siddha Vaidyasala, Thiruvananthapuram	Departmental Action
2	Dasamoolarishtam	Kerala Sarvodaya Pharma, Thiruvananthapuram	Departmental Action
3	Yograjagulgulugulika Tablet	VaidyaratnamOushadhasalaPvt.Ltd, Thrissur	Departmental Action
4	PushyanugaChoornam	K.P. PathroseVaidyansKandamkulathiVaidyasala, Thrissur	Departmental Action
5	Lucocare	K.P. PathroseVaidyansKandamkulathiVaidyasala, Thrissur	Departmental Action
6	ThamboolaRasayanam	siddhasramam Sivananda VijayamOushadhasala, Thiruvananthapuram	Departmental Action
7	A D Capsule	Vasudevavilasom Herbal Remedies, Thiruvananthapuram	Departmental Action
8	Varachooram	Vasudevavilasom Herbal Remedies, Thiruvananthapuram	Departmental Action
9	VaiswanaraChoornam	Vasudevavilasom Herbal Remedies, Thiruvananthapuram	Departmental Action
10	KasthuriKalpamarit ham	Agasthya Pharmaceuticals, Thiruvananthapuram	<b>Case Filed</b>
11	Vatayog coated Tab	Arya AushadhiPharmaceuticals, Indore	Departmental Action
12	Exitox Tab	Apoorva Vaidya, Kottayam	Departmental Action
13	SwasanandamGulika	MangoladyamPharmaceuticals, Malappuram	Departmental Action
14	AvipathiChoornam	S D Pharmacy, Alappuzha	Departmental Action
15	Chyavanaprasam	Palm Labs Ernakulam	Departmental Action
16	Heemobix	Palm Labs Ernakulam	Departmental Action
17	GugguluTikthakam	Palm Labs Ernakulam	Departmental Action
18	Herbix Cough Syrup	Palm Labs Ernakulam	Departmental Action
19	Dioset Capsules	Sankar Pharmacy, Ernakulam	Departmental Action
20	AgasthyaRasayanam	Bodhi Pharmacy, Ernakulam	Departmental Action
21	ThaleesapathradiChooram	Payattuthara Clinic & Pharmacy, Ernakulam	Departmental Action
22	Mushtarishtam	Alappat Pharmacy, Kollam	Departmental Action

23	Dasamoolarishtam	Alappat Pharmacy, Kollam	Departmental Action
24	Partharishtam	AlappatPharmacy,Kollam	Departmental Action
25	Amritharishtam	AlappatPharmacy,Kollam	Departmental Action
26	GorochandiGulika	ChaithanyaAyurvedics, Thiruvananthapuram	Departmental Action
27	Mukkamukkuduvat hiGulika	Vaidya Ratnam Ps Variers , Thrissur	Departmental Action
28	PushyanugaChoornam	The Pharmaceutical Corporation Kerala Limited, Thrissur	Departmental Action
29	Karimjeerakam	PKM. Ayurveda Hospital & Pharmaceuticals, Kannur	Departmental Action
30	Haridrakhandam	The Pharmaceutical Corporation Kerala Limited, Thrissur	Departmental Action
31	VilwadiGulika	Pattiyam Social Service Society, Kannur	Departmental Action
32	GopichandanadiGulika	Vaidya Ratnam Ps Variers Thrissur	Departmental Action
33	MandooraVadakam	MVSAyurvedic Research Centre, Malappuram	Departmental Action
34	Metascab Ointment	Trio Health care Private Limited, Ahemmadabad	Departmental Action
35	Vayamb	Kurumathur Arya Aidyasala and Nursing Home , Kannur	Departmental Action
36	Katurohini	Kurumathur Arya Aidyasala and Nursing Home , Kannur	Departmental Action
37	Muthanga	Kurumathur Arya Aidyasala and Nursing Home , Kannur	Departmental Action
38	Lung Care for easy breath	Pattiam Social service Society Limited, Kannur	Departmental Action
39	Sakthivita general tonic Pills	Herbal Pharmacy Cherukattoor, Wayanadu	Departmental Action
40	Satavari	Siddhasramam Sivananda VijayamOushadhasala, Kannur	Departmental Action
41	Rexfort Capsules	Prince Ayurveda Pharmacy, Kolar, Karnataka	<b>Case Filed</b>
42	GorachanadiGulika	Viswakeerthi Herbals, Malappuram	Departmental Action
43	SwasanandamGulika	ViswakeerthiHerbals,Malappuram	Departmental Action
44	Vizhalari	Malabar Ayurvedasramam, Kasargod	Departmental Action
45	Triple X Power	Win Trust Pharmaceuticals , Ludhiyana	<b>Case Filed</b>
46	Athivere	Abdurahiman(As per Coplaint on illegal medical practice),Kasargod	Departmental Action
47	Dhanwantharam Gulika	KadathanaduAyurvedics, Kozhikode	Departmental Action
48	ChandraprabhaGulika	SNA Oushadasala Pvt. Ltd., Thrissur	Departmental Action

49	RajanyadiChoornam	Arya Vaidya Pharmacy Coimbatore Ltd, Palakkad	Departmental Action
50	Pipalyasavam	Manayath Ayurveda, Kozhikode	Departmental Action
51	Vaiga Syrup	Vedamini Arya Vaidyasala, Kozhikode	<b>Case Filed</b>
52	Clean Hand Sanitizer	Mahavir Health Care, Hisar, Hariyana	Departmental Action
53	VaigaSyurup	Vedamini Arya vaidyasala, Kozhikode	Departmental Action
54	Super Cofse Hand Sanitizer	Harkesav Ayurveda, Baswal	Departmental Action
55	Kineaz	Arya vaidyaVilasiniVaidyasala, Kozhikode	<b>Case Filed</b>
56	Abhayarishtam	Sreekumaramemmorial Ayurveda Pharmacy, Kollam	Departmental Action
57	Jeerakarishtam	Sreekumaramemmorial Ayurveda Pharmacy, Kollam	Departmental Action
58	Amritharishtam	Sreekumaramemmorial Ayurveda Pharmacy, Kollam	Departmental Action
59	Abhayarishtam	SDV manufacturing, Kollam	Departmental Action
60	Balarishtam	Changethu Herbs drugs, Pathanamthitta	Departmental Action
61	Dasamoolarishtam	Alappat Pharmacy, Kollam	Departmental Action
62	Balarishtam	Buddha Herbals, Pathanamthitta	Departmental Action
63	Chyavanaprasam	SDV manufacturing, Kollam	Departmental Action
64	Saribadyasavam	Kerala Ayurveda Ltd, Ernakulam	Departmental Action
65	Dasamoolarishtam	Jayalakshmi Pharma ,Kollam	Departmental Action
66	Amritharishtam	Jayalakshmi Pharma , Kollam	Departmental Action
67	Abhayarishtam	Jayalakshmi Pharma , Kollam	Departmental Action
68	Amritharishtam	Alappat Pharmacy, Kollam	Departmental Action
69	Abhayarishtam	Alappat Pharmacy, Kollam	Departmental Action
70	Kudajarishtam	Alappat Pharmacy, Kollam	Departmental Action
71	Ashokarishtam	Alappat Pharmacy, Kollam	Departmental Action
72	Punarnavasavam	Alappat Pharmacy, Kollam	Departmental Action
73	Abhayarishtam	Balaherbs, Kollam	Departmental Action
74	HingveshtakaChooranam	Petland mahal Arogya mandal Pharmacy, Gujarath	<b>Case Filed</b>

75	Amrithaguggulu tablet	Nagarjuna Herbal Conentrats Ltd., Idukki	Departmental Action
76	ThirumeniMehamu ktha	Thirumeni Products, Thrissur	<b>Case Filed</b>
77	GuloochyadiChoor nam	Thirumeni Products, Thrissur	<b>Case Filed</b>
78	CREA-T-N	Thirumeni Products, Thrissur	<b>Case Filed</b>
79	VaiswanaraChoorn am	AshtavaidyanThaikkattumoossVaidyaratnamOushadhasa la, Thrissur	Departmental Action
80	Haridrakhandam	Vaidyaratnam Ps Variers Aryavaidiasala, Palakkad	Departmental Action
81	Tox Out Tabs	Palm Labs Ernakulam	Departmental Action
82	Utibix Caps	Palm Labs Ernakulam	Departmental Action
83	Nasomed Tablets	Palm Labs Ernakulam	Departmental Action
84	Orbix Capsule	Palm Labs Ernakulam	Departmental Action
85	Diabix Tab	Palm Labs Ernakulam	Departmental Action
86	Rumato-Ds Capsule	Hitech Herbaals , Tamil Nadu	<b>Case Filed</b>
87	VS Lehyam	Sankar Pharmacy, Ernakulam	Departmental Action
88	Psorex Oil	Sankar Pharmacy, Ernakulam	Departmental Action
89	Karukapatta	Sankar Pharmacy, Ernakulam	Departmental Action
90	MaharasnadiKwath	Kerala Ayurveda Ltd, Ernakulam	Departmental Action
91	NisakathakadiKwath	Kerala Ayurveda Ltd,Ernakulam	Departmental Action
92	NimbadiKwath	Kerala Ayurveda Ltd,Ernakulam	Departmental Action
93	IndukanthamKwath	Kerala Ayurveda Ltd,Ernakulam	Departmental Action
94	RasnasapthakamKwath	Kerala Ayurveda Ltd,Ernakulam	Departmental Action
95	AmruthotharamKwath	Kerala Ayurveda Ltd,Ernakulam	Departmental Action
96	PushyanugaChoorn am	Vaidya Ratnam Ps Variers Aryavaidiasala, Palakkad	Departmental Action
97	Kurumulaku	Palm Labs Ernakulam	Departmental Action
98	Manjal	Palm Labs Ernakulam	Departmental Action
99	Njerinjil	Palm Labs Ernakulam	Departmental Action
100	AvanakkinVeru	Palm Labs Ernakulam	Departmental Action



101	HinguvachadiGulika	K.P. PathroseVaidyansKandamkulathiVaidyasala, Thrissur	Departmental Action
102	GopichandanadiGulika	K.P. PathroseVaidyansKandamkulathiVaidyasala, Thrissur	Departmental Action
103	Arthrum Oil	Vital care Pvt.Ltd, Vadodara, Gujarath	Departmental Action
104	Happy Hours	Kerala Sarvodaya Pharma, Thiruvananthapuram	<b>Case Filed</b>
105	Purest Advance Hand Sanitizer	Colorchem Industries, Indore	<b>Case Filed</b>
106	Pain NiwaranaChurna	Rajasthan Herbals International Pvt Ltd, Rajasthan	<b>Case Filed</b>
107	Dr.Relaxi Capsule	Rajasthan Herbals International Pvt Ltd, Rajasthan	<b>Case Filed</b>
108	Ortho care	SB Pharmaceutical Laboratories, Ernakulam	Departmental Action
109	SurariChoorna	Rajasthan Herbals International Pvt Ltd, Rajasthan	<b>Case Filed</b>
110	Asthalex Capsule	Rajasthan Herbals International Pvt Ltd, Rajasthan	<b>Case Filed</b>
111	DamaButtiChurna	Rajasthan Herbals International Pvt Ltd, Rajasthan	<b>Case Filed</b>
112	Myaxyl Oil	Kerala Ayurveda Ltd, Ernakulam	Departmental Action
113	Sb Vitta Capsule	SB Pharmaceutical Laboratories, Ernakulam	Departmental Action

## Annexure-II

State government of Mizoram informed that out of 278 ASU & H Drugs samples tested during April- November, 2022, 4 samples (02 Ayurvedic & 02 Homoeopathic drugs) were found to be non-compliant with the Drugs and Cosmetics Act, 1940. These 2 Ayurvedic drugs are:

i) Mutra Vahani Capsule (Ayurvedic Proprietary Medicine).

Date of Receipt : 01/09/2022

Sample Batch No. : MSE 363

Note : The Capsule was embedded alongwith the metal strip and the nature of the capsule which was designed to have hard capsule was observed to have elasticity or rubberiness which indicates the packaging was not of Standard Quality. Thus the drug is concluded to be Misbranded according to Drugs & Cosmetics Act, 1940 Chapter IV A Rule 33 E.

ii) Gain More Powder (Ayurvedic Proprietary Medicine)

Date of Receipt : 01/09/2022

Sample Batch No.: GM- 001

Note: The total number of microbial colonies per 1 gram of sample was found to be too numerous to count (TNTC). This value highly exceeds the standard value, i.e,  $1 \times 10^5$  cfu/g according to Ayurvedic Pharmacopoeia of India, Part 1, Vol. 6, Page No. 266- 280. The contaminants was cultured on Ceftrimide, MacConkey and Brilliant Green Agar medium which shows the absence of Gram negative bacteria viz., E. Coli, Salmonella and Pseudomonas aeruginosa. Gram staining was performed and the contaminants were found to be of Gram negative rod under microscopic observation at 100 X oil immersion.

**Annexure-III**

<b>Drugs tested as Not of Standard Quality (NSQ) during 01.04.2021 to 31.10.2022.</b>					
S.no.	Sample name	Name of the Manufacturer	Manufacturing state	FDL result (NSQ-Not of standard)	Date of the sample withdrawn
1.	Ichha bhedi ras AFI	Shilpachem	Madhya Pradesh	NSQ	26/09/2019
2.	Asmo churn	Rushabh medicines	Maharashtra	NSQ	22/09/2021
3.	Rumon tablet	Rushabh medicines	Maharashtra	NSQ	22/09/2021
4.	Maha narayan taila	Amrut pharmaceuticals	Karnataka	NSQ	30/03/2019
5.	Leptaden	Mis alarsin	Gujrat	NSQ	28/02/2022
6.	Small polythine pouch containing black color tablet purporated to be ayurvedic medicine used for joint pain	Not stated	Other state	NSQ	20/07/2022
7.	Big polythine pouch containing orange color crystals purporated to be ayurvedic medicine used for joint pain	Not stated	Maharashtra	NSQ	20/07/2022
8.	Rumon tablets	Rushabh medicines	Maharashtra	NSQ	31/08/2021
9.	Rumon tablet	Rushabh medicines	Maharashtra	NSQ	22/09/2021
10.	Grmsil hand sanitizer	Shree ganesh ayurvedic pharma,	Maharashtra	NSQ	28/09/2021
11.	Purest advanced hand sanitizer	Colorchem industries ltd.	Madhya Pradesh	NSQ	4/1/2021
12.	Sb cleanser herbal hand sanitizer 70% ethyl alcohol	Shri brahmachaitanya ayurved	Maharashtra	NSQ	12/5/2021
13.	Trikuta hand safe hand sanitizer	Trikuta medicare	Madhya Pradesh	NSQ	19/11/2021
14.	Mugale azam 3x cap	Al-kousar pharma	Tamil Nadu	NSQ	23/11/2021
15.	Giloy ghanvati an ayurvedic proprietary medicine	Alixion pharmaceutical india pvt. Ltd.	Haryana	NSQ	6/12/2021

16.	Eno fruit salt lemon flavour	Legacy food pvt.ltd.	Himachal pradesh	NSQ	29/11/2021
17.	Suvarnaprash with gold drop	Tanvi health care	Gujrat	NSQ	11/2/2020
18.	Arthowin capsules	Birla pharmaceuticals (pvt.) Ltd	Rajsthan	NSQ	23/12/2021
19.	Medari tablets	Abhay ayurvedic pharmacy	Maharashtra	NSQ	18/11/2019
20.	Todkar sanjivani sujivaniy churna	Chaitrali herbocos	Maharashtra	NSQ	8/12/2020
21.	Sanisafe hand rub	Royal bengal health care	Gujrat	NSQ	22/12/2021