GOVERNMENT OF INDIA MINISTRY OF AYUSH

RAJYA SABHA UNSTARRED QUESTION NO. 815 TO BE ANSWERED ON 30th July 2024

"Status of AYUSH drug manufacturing in the country"

815. Shri. K. R. N. Rajeshkumar

Will the Minister of *Ayush* be pleased to state:

- (a) the schemes implemented, and methodology established to ensure quality control and standardization of AYUSH drugs;
- (b) whether any action was taken in the last five years against misleading advertisements for treatment and drugs, if so, the details thereof; and
- (c) whether there are any subsidies or incentives for manufacturing AYUSH drugs and, if so, the details thereof?

ANSWER

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

- (a) and (c) In the year 2021, Ministry of Ayush has implemented a Central Sector Scheme Ayush Oushadhi Gunavatta evam Uttpadan Samvardhan Yojana (AOGUSY). The total financial allocation to this scheme is Rs. 122.00 crores for five years. The components of AOGUSY scheme are as follows: -
- A. Strengthening and up-gradation of Ayush Pharmacies and Drug Testing Laboratories to achieve higher standards.
- B. Pharmacovigilance of ASU&H drugs including surveillance of misleading advertisements.
- C. Strengthening of Central and State regulatory frameworks including Technical Human Resource & Capacity Building programs for Ayush drugs.

D. Support for development of standards and accreditation/certification of Ayush products & materials in collaboration with Bureau of Indian Standards (BIS), Quality Control of India (QCI) and other relevant scientific institutions and industrial R&D centers.

The objectives of the Scheme are as under;

- i. To enhance India's manufacturing capabilities and exports of traditional medicines and health promotion products under the initiative of Atmanirbhar Bharat.
- ii. To facilitate adequate infrastructural & technological upgradation and institutional activities in public and private sector for standardization, quality manufacturing and analytical testing of Ayush drugs & materials.
- iii. To strengthen regulatory frameworks at Central and State level for effective quality control, safety monitoring and surveillance of misleading advertisements of Ayush drugs.
- iv. To encourage building up synergies, collaborations and convergent approaches for promoting standards and quality of Ayush drugs & materials.

Detailed guidelines of AOGUSY scheme are available at https://ayush.gov.in/images/Schemes/aoushdhi.pdf

Further for release of Grand-in-aid All India Institute of Ayurveda, New Delhi, AIIA is designated as Central Nodal Agency. The details of grant are annexed as **Annexure-I.**

The Drugs & Cosmetics Act, 1940 and Rule made there under have exclusive regulatory provisions for Ayurvedic, Siddha, Unani, and Homoeopathy drugs. Provisions relating to Ayurveda, Siddha and Unani Drugs are contained in Chapter IVA and Schedule- I of the Drugs and Cosmetics Act, 1940 and in Rules 151 to 169, Schedules E(I), T & TA of the Drugs and Cosmetics Rules, 1945. Further Second Schedule (4A) of the Drugs and Cosmetics Act, 1940 provides standards for Homoeopathic drugs and Rules 2dd, 30AA, 67 (C-H), 85 (A to I), 106-A, Schedule K, Schedule M-I of the Drugs and Cosmetics Rules, 1945 pertain to Homoeopathic drugs. 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 & Schedule M-I of

Drugs and Cosmetics Rules, 1945 and quality standards of drugs given in the respective pharmacopoeia.

(b) Pharmacovigilance Centres for Ayurveda, Siddha, Unani and Homoeopathy (ASU&H) Drugs set up in different parts of the country under the Central Scheme of Ministry of Ayush are mandated to monitor and report the misleading advertisements to the respective State Regulatory Authorities. The program is working through a three-tier network of a National Pharmacovigilance Centre (NPvCC), Five Intermediary Pharmacovigilance Centers (IPvCs) and 99 Peripheral Pharmacovigilance Centers (PPvCs) established across the country. All India Institute of Ayurveda (AIIA), New Delhi under Ministry of Ayush is the National Pharmacovigilance Co-ordination Centre (NPvCC) for the implementation of the National Pharmacovigilance program for Ayurveda, Siddha, Unani & Homoeopathy drugs. Objectionable advertisements are being reported to the respective State Licensing Authorities by PPvC at regular intervals.

The vision of the program is to improve patient safety in Indian population by monitoring the drug safety in ASU & H drugs and thereby reducing the risk associated with use of these drugs. Further, the program focusses upon generating awareness among various stakeholders, inculcating reporting culture of suspected adverse effects and surveillance of misleading advertisements appearing in the print and electronic media. To generate awareness regarding the Ayush therapeutic approaches and educate about the systematic use of Ayush drugs, and to inculcate the reporting of any suspected adverse drug reaction in healthcare professionals; awareness events are being regularly organized across the country. Since 2018, the center has started receiving suspected reactions. These are the individual case safety reports and can be signals for future reference. These are being recorded and submitted to Drug Policy Section, Ministry of Ayush for information. Reporting Objectionable advertisements to the respective State Licensing Authorities are an objective of the program.

Under the Pharmacovigilance program till date a total of 38539 misleading advertisements related to Ayush drugs has been noticed and reported to the SLAs for possibility of action against the defaulter's details are available at Annexure-II.

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 self-limiting and non-serious in nature.

Also, as per National Commission for Indian System of Medicine Regulations, 2022 and National Commission for Homoeopathy regulations, 2022, Pharmacovigilance is a mandate component for all the Ayush system of medicine. Also, 1500 awareness programs have been conducted with 115283 beneficiaries,

The details of action taken in the last five years against misleading advertisements for treatment and drugs are available in **Annexure-III.**

Annexure-I

Details of Funds Released under AOGUSY Central Sector Scheme

S. N		_		Pharmacy/		Amount
0.	F.Y.	State	Component	DTL	Particulars	released
1	2021-22	Mizoram	Strengthening and up-gradation of Ayush Pharmacies and Drug Testing Laboratories to achieve higher standards	DTL	State Govt. of Mizoram	18,00,000
2	2021-22	New Delhi	Pharmacovigilance of ASU&H drugs including survellance of misleading advertisements	-	All India Institute of Ayurveda, New Delhi	2,72,40,000
3		New Delhi	Pharmacovigilance of ASU&H drugs including survellance of misleading advertisements	-	All India Institute of Ayurveda, New Delhi	4,30,52,000
4		Pune		Pharmacy	Inducare Pharma Pvt.Ltd. Pune	3,00,00,000
5		Maharashtra		Pharmacy	Ayurchem Private Ltd. Maharashtra.	2,69,00,000
6	2022-	Maharashtra	Strengthening and	Pharmacy	Phytovedic India Pvt. Ltd. Maharashtra	2,14,61,000
7		Kerela	up-gradation of Ayush Pharmacies	Pharmacy	Visesh Ayurvedic Pvt. Ltd Pharmacy Kerala.	1,91,56,000
8		Uttar Pradesh	and Drug Testing Laboratories to	Pharmacy	Amar Pharmaceuticals and labs (I) Pvt. Ltd. U.P	1,43,43,000
9		Uttar Pradesh	achieve higher standards	DTL	Amar Pharmaceuticals and labs (I) Pvt. Ltd. U.P (DTL)	77,67,000
10		Madhya Pradesh		Pharmacy	Shree Baidyanath Ayurved Bhawan Pvt. Ltd, Madhya Pradesh	2,08,92,000

11		Kerela		Pharmacy	Kollam District Ayurveda Oushdha Nirmana Vyavasaya Co- operative Society Ltd, Kerela	64,29,000
12		Tripura	Strengthening and up-gradation of Ayush Pharmacies and Drug Testing Laboratories to achieve higher standards	DTL	State Govt. of Tripura	76,68,000
13		Madhya Pradesh	Strengthening and up-gradation of Ayush Pharmacies and Drug Testing Laboratories to achieve higher standards	Pharmacy	Shree Baidyanath Ayurved Bhawan Pvt. Ltd, Madhya Pradesh	91,08,000
14	2023- 24	Jammu & Kashmir	Strengthening and up-gradation of Ayush Pharmacies and Drug Testing Laboratories to achieve higher standards	DTL	State Govt. J&K	86,29,500
15		New Delhi	Pharmacovigilance of ASU&H drugs including survellance of misleading advertisements	-	All India Institute of Ayurveda, New Delhi	3,75,12,872
16		New Delhi	Pharmacovigilance of ASU&H drugs including survellance of misleading advertisements		All India Institute of Ayurveda, New Delhi	3,36,75,126
17		Kerela	Strengthening and up-gradation of	Pharmacy	Sitaram Ayurveda Pvt. Ltd, Thrissur, Kerala.	50,00,000
18		Kerela	Ayush Pharmacies and Drug Testing	Pharmacy	Pankajakasthuri Herbals India Private Limited,	50,00,000

			Laboratories to		Poovachal, Kerala	
19		Rajasthan	achieve higher standards	Pharmacy	BJain Pharmaceuticals Private Limited, Alwar, Rajasthan	50,00,000
20		Assam		Pharmacy	Assam Ayurvedic Products, Guwahati, Assam	45,59,519
21		Jammu & Kashmir		Pharmacy	Govt. Pharmacy, Jammu & Kashmir	1,05,00,000
22		Guajarat		Pharmacy	State Pharmacy, Rajpipla, Gujarat	44,20,248
23		Mizoram		DTL	State Govt. Drug Testing Laboratory, Mizoram	67,20,884
24		Tamil Nadu		DTL	State Govt. Drug Testing Laboratory, Tamil Nadu	20,00,000
25		Arunachal Pradesh		Pharmacy	State Pharmacy, Arunachal Pradesh	67,02,164
26		Arunachal Pradesh		DTL	State Drug Testing Laboratory , Arunachal Pradesh	17,99,813
27		Arunachal Pradesh	Strengthening and	Pharmacy	State Pharmacy, Arunachal Pradesh	70,42,077
28	2024- 25	Arunachal Pradesh	up-gradation of Ayush Pharmacies and Drug Testing Laboratories to achieve higher standards	DTL	State Drug Testing Laboratory, Arunachal Pradesh	17,24,400
29		Kerela		Pharmacy	Pankajakasthuri Herbals India Private Limited, Poovachal, Kerala	44,32,807
					Total	38,05,35,410

Annexure-II

Details of misleading advertisements related to Ayush drugs noticed by Pharmacovigilance and reported to the SLAs are as follows:

Year	Misleading Advertisements
2018	411
2019	4395
2020	5861 + 171 (COVID)
2021	8144 + 43 (COVID)
2022	7367 + 4 (COVID)
2023	7771
2024	4372
Total	38539

Action taken against reported Misleading Advertisements

Annexure-III

Month	Name of the Centre	State	No of Misleading Advertisement	Name of the product	Action taken by SLA
August 2020	Uttarakhand Ayurved University Dehradun	Uttrakhand	15	Ayush kwath, Divya coronil, divya swasari vati, denguinil vati, muktanil vati, jwarnasak vati, mahasudarshan vati, ghan vati, japani M & f cap, right sugar tab, ashoka ayu. Syp.,Sacchi saheli, Roop matra, Himfort Oil	Notice has been sent to the advertiser
September 2020	National institute of Ayurveda, Jaipur Rajasthan Ayurveda University, Jodhpur	Rajasthan	11	Eye mantra eye drops-2, Dr ortho oil spray, Roop mantra-2, Ichku lotion, madhushunya churna, sachhi Saheli, Tulsi drop 51, zalim lotion, collogin cream,	Notice has been sent to the advertiser
October 2020	National institute of Ayurveda, Jaipur Rajasthan Ayurveda University, Jodhpur	Rajasthan	11	Collegian Ayurvedic Cream, shilapravang, JolyTulsi 51 Drops, Vasir Gel & Capsule, Tulsi-51, Fat Go Capsule, Torex Herbal Cough Syrup, SACHHI SAHELI Syrup, Tablet	Notice has been sent to the advertiser
November 2020	National institute of Ayurveda, Jaipur	Rajasthan	1	Kesh King Ayurvedic Hair oil	Notice has been sent to the advertiser
January 2021	National institute of Ayurveda, Jaipur Rajasthan Ayurveda University, Jodhpur	Rajasthan	1	Kasturi gold & ling vartdhak cream.	Notice has been sent to the advertiser
	H. S. Z. H. Govt. Unani	Madhya Pradesh	10	Isotin gold plus,shababiya,cap more power,BT-36 cap, ketomac	Notice has been sent to

	Medical College & Hospital,			oil,dabar tulsi drop,roop mantra, acumass,jolly tulsi drop,tulsi mantra	the advertiser
	Bhopal National institute of Ayurveda, Jaipur Rajasthan Ayurveda University, Jodhpur	Rajasthan	15	Eye mantra, Dr ortho, Roop mantra, Ichku lotion, Tulsi giloy juice, zalim lotion, , japani M & f cap, right sugar tab, Chaturbhuj cap, isotin eye drop, pet safa, fat go cap, collegin cream, right sugar tab.	Notice has been sent to the advertiser
February 2021	Govt. Hospital (Siddha Wing), Erode Govt. Hospital,			Arogya plus detox dinner tea, kabasura kudineer, thamara 20 Nilavembu kudineer,kabasura kudineer	
	Kamuthi Govt. Hospital Dindigul	Tamilnadu	25	Dr m gurubran,dr m sabapati,agasthiyar madhumega cap.,dr vishwanath,dr N.K.dikkhatar,dr shivanantum,dr B.A. rai,dr P.dhilesh,dr k rajsekharan,dr m senthikumari,vaithiyar g. ananthan,dr k purushotaram,dr M mugamadu meeran	Notice has been sent to the advertiser
March 2021	National institute of Ayurveda, Jaipur Rajasthan Ayurveda University, Jodhpur	Rajasthan	19	Sanyasi sehat tab.,Ichku lotion, kidney rogiyo ke aasha ki kiran,chaturbhuj tail & tab,julfraj, petsafa,japani tail,sacchi saheli,dr ortho,hempushpa,swarnamadhu	Notice has been sent to the advertiser
April 2021	National institute of Ayurveda, Jaipur Rajasthan Ayurveda University, Jodhpur	Rajasthan	6	Fatgo tab,sacchi saheli,velica tulsi drop,immunity builder drop,curequovita immunity booster	Notice has been sent to the advertiser
	Govt. hospital kuzhutharai	Tamilnadu	3	Nilavambu kudineer,ulcer heal churnam,kabasura kudineer	

May 2021	National institute of Ayurveda, Jaipur Rajasthan Ayurveda University, Jodhpur	Rajasthan	8	Navgrah immunity booster,velcia tulsi drop,curative immunity drop, mess. Dhanwantari pharma,navivaha unmantha,shukla asar implex,shrinavjeevan rasayan,P- 6 cap	Notice has been sent to the advertiser
June 2021	National institute of Ayurveda, Jaipur Rajasthan Ayurveda University, Jodhpur	Rajasthan	10	Sanyasi Ayurveda, akums drugs & pharma,pure & cure health care, shukla ashar implex pvt ltd,unjha pharnma, dindayal industry,P-6 Cap,derma kit.	Notice has been sent to the advertiser
	H. S. Z. H. Govt. Unani Medical College & Hospital, Bhopal	Madhya Pradesh	4	She care,shababiya,prost ad tab, isotin drop	Notice has been sent to the advertiser
July 2021	Central Ayurveda Research Institute, Kolkata	West Bengal	4	Roop mantra,eye mantra,sacchi saheli, D.ortho	Notice has been sent to the advertiser
	National institute of Ayurveda, Jaipur Rajasthan Ayurveda University, Jodhpur	Rajasthan	22	Kesh king,immunity booster drop,chawanprash,velcia pure tulsi ds tab,ferroliv E tab,ayush kwath churna,ashokarista,roopmantra,dr skin lotion,sanyasi sehat tab,ichku lotion,pet safa,sacchi saheli,take piles,jeevan kailash,kasamrit,D.ortho,P-6 cap	Notice has been sent to the advertiser
August 2021	National institute of Ayurveda, Jaipur	Rajasthan	12	Paralysis treatment-2, Kidney specialist, Eye Mantra Eye Drops, Collagian Cream-2, Dabur Tulsi, Hempushpa, Gyneafort, Accumass, Isotine Eye Drops, Ichkoo Lotion, Sacchii Saheli, Dr.Ortho, Acumass.	Notice has been sent to the advertiser
November 2021	H. S. Z. H. Govt. Unani	Madhya Pradesh	3	Eye Mantra, She care, Hempushpa	Notice has been sent to

	Medical College & Hospital, Bhopal				the advertiser
	Govt. Siddha Medical College, Palayamkottai	Tamil	1	Obesity reduction product	SLA of Tamil Nadu wrote to Registrar of Tamil Nadu Siddha Medical Council to take appropriate action.
	PPvC, Perundurai GH (Siddha Wing), Erode	Nadu	Nadu 1	Kabasura Kudineer Chooranam	SLA of Tamil Nadu wrote to Commissioner of Food Safety, FSSAI, Chennai to take appropriate action.
December 2021	Govt. Hospital, (Siddha Wing), Kamuthi	Tamil Nadu	1	Almaa Brand S.S. Elagam	SLA of Tamil Nadu wrote to Commissioner of Food Safety, FSSAI, Chennai to take appropriate action.
January 2022	National institute of Ayurveda, Jaipur Rajasthan Ayurveda University, Jodhpur	Rajasthan	8	Sudol Body Toner, Japani Tail-2, Kesari Malham, Iso Plus Oil, Hawaban Harde, SwarnMadhu Syrup, Jagravi Churn.	Notice has been sent to the advertiser
February 2022	National institute of Ayurveda, Jaipur	Rajasthan	8	Techpiles, Dr.Ortho, Pet Saffa, Kesari Malham, Acumass, Iso Plus Oil, Dhuandhaar Oil, Kamarti Oil	Notice has been sent to the advertiser

	Rajasthan Ayurveda University, Jodhpur				
March 2022	National institute of Ayurveda, Jaipur Rajasthan Ayurveda University, Jodhpur	Rajasthan	6	Trichep Hair Oil, Iso Plus Oil, Kesh KingHair Oil, Kesari Malham, Tanam Syrup, Hawa Band.	Notice has been sent to the advertiser
April 2022	National institute of Ayurveda, Jaipur Rajasthan Ayurveda University, Jodhpur	Rajasthan	11	Iso Plus Oil-2, Kamrati Gel, Dhuandhar Oil-2, Kesh King, Kesari Malham, Tanam Syrup, Collagian Cream, B-Gap, Ajoobi Balm, Ichkoo Lotion.	Notice has been sent to the advertiser
May 2022	National institute of Ayurveda, Jaipur Rajasthan Ayurveda University, Jodhpur	Rajasthan	15	Sachhi Saheli, Accumass, Isotine, Taasav Arisht, B-Gap-2, Collagian Cream, Mughali GHutti, Navratan Oil, Vithoba, Kesh King, Emami-2, Iso Plus, B.T. 36 Capsules, Prem Dulhan Heena Hair.	Notice has been sent to the advertiser
June 2022	National institute of Ayurveda, Jaipur Rajasthan Ayurveda University, Jodhpur	Rajasthan	6	Restora Gold, BT 36 Capsule, Esarer Capsules, Sundari Sudha, Mahabhrangraj, Sudol Body Toner.	Notice has been sent to the advertiser
July 2022	National institute of Ayurveda, Jaipur Rajasthan Ayurveda University, Jodhpur	Rajasthan	9	Chawanprash, Rasayan Vati, Restora Gold, Livosin Syrup, Accumass, Dr.Ortho, Paralysis Treatment, Eye Mantra, Kidney Treatment.	Notice has been sent to the advertiser

August 2022	National institute of Ayurveda, Jaipur Rajasthan Ayurveda University, Jodhpur	Rajasthan	6	Beone, Isotine, Mastang Capsule-2, Good Hair.	Notice has been sent to the advertiser
October 2022	IPVC, NIUM, Bangalore	Bengaluru	15	Soma Gynoveda, Carcin tablet, Lingavardhaka yantra & Kamadeva cream, Stay on power capsule, Renal activator, Astra Herbals, pet safa granules, Lavana Tailam, Sachi Saheli, Jataa, Amrutha Bindu, Lavana Taila, Dr. Juneja Eye drops, Itchku, medohar guggulu	Notice has been sent to the advertiser
	IPVC, NIUM, Bangalore	Bengaluru	15	Shivatra Nashak, Dhanwabthri Ayurveda, Pet Saffa, Glutone Thousand, Jeehab Gynoveda, Ichkoo, Gyniveda Saomha, Eye Mnatra, Lingavardhaka, Japani M Caps, Hynoveda Myrha & Vamha	Notice has been sent to the advertiser
November 2022	National institute of Ayurveda, Jaipur Rajasthan Ayurveda University, Jodhpur	Rajasthan	9	Pachak Amrit, Meghdoot sareetha, Mahabhringraj Oil, Kasmadhu herbal cough syrup, Himalaya Neem Face Wash, Torex Cough Syrup, Divya Swasari Gold, Kayam Churna, Breast Maker 36 oil, Japani M Oil.	Notice has been sent to the advertiser
December 2022	National institute of Ayurveda, Jaipur Rajasthan Ayurveda University, Jodhpur	Rajasthan	5	Dr.Ortho, Right Sugar, Kesari Malham, Ichkoo, Torex Cough Syrup.	Notice has been sent to the advertiser
	RARI, Gwalior	Madhya Pradesh	4	Kayam Churna, Arodent, Eraser Cream, Pet Saffa	Notice has been sent to the advertiser

	RARI, Gwalior	Madhya Pradesh	4	Japani Tail, Vigroman, Ichkoo, Chaturbhuja Tailum	Notice has been sent to the advertiser
January 2023	NIUM, Bangalore	Bengaluru	14	Not Mentioned, Stay On, DrJuneja Eye Drops, Lingavardhaka, Japani M Capsules, Tulha Ayurvedic Tablet, Pet Safa, Japani Oil, Dr.Ortho, Dona Gynoveda, Advanced Ayurvedic Unani & Naturopathy, Kidney Auxilium Capsules	Notice has been sent to the advertiser
	ITRA, Jamnagar	Kolkata	1	Flamcon	Suspension of drug license
February 2023	NIUM	Bangalore	18	Not mentioned, Dr.Ortho, Sachi Saheli, Unani Treatment-2, Indian Ayurveda, Stayon Power Capsule, Eye Mantra, Leuco relief & She tone Syrup, Jawahar Murakkab, Ayuvedic & Unani Medicine-3, Hayat-e-Mard, Active Power Capsule, Unani Treatment, Linga Vardhaka Yantra & Kamadeva Cream,	Notice has been sent
		Madhya Pradesh	02	Eye Mantra, Brumex Fort	
March 2023	NIUM	Bangalore	13	Rasha-Rid, Noorament oil & Cream, Navyavaanna Dispensary-2,Eye Mantra, Dr. Yasir Unani, Stay-On Power Oil, Sacchi Saheli, Herbanova, Braino Tonic, Hayat-e-Mard, Abdullah Pathan Official	Notice has been sent
	NIA	Jaipur	07	Dhanwantri Pharmaceuticals-2, Dr. Ortho, Kailash Jeevan, Name not mentioned-2, Accumass granules.	Notice has been sent
April 2023	NIUM	Bangalore	12	Eye Mantra, Dr. Ortho, Sachi Saheli, Obecop Vstaarplus, Pilocop Pravahi Kwath, Fervidcop, Stonocop, Gynecop, Cardiocop, Thyrocop, No product name-2	Notice has been sent
May 2023	NIUM	Bangalore	07	Kanchnar Guggulu, Womens immunity, Waseerkalp, Phytolacca, Namira Weight	Notice has been sent

			Loss, Vatchintamani, Cruel Capsule	
Total			378	

State wise total Action Taken by SLA upto July 2024

S.No.	STATE	TOTAL SLA ACTION TAKEN
1	Karnataka	94
2	Madhya Pradesh	27
3	Rajasthan	206
4	Tamil Nadu	31
5	Uttarakhand	15
6	West Bengal	5
Total		378
