

GOVERNMENT OF INDIA
MINISTRY OF AYUSH
RAJYA SABHA
STARRED QUESTION NO. 110
TO BE ANSWERED ON 10th February 2026

Clinical trials and treatment protocols for AYUSH formulations

110 Shri Ravi Chandra Vaddiraju:

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

- (a) whether Government has taken note of concerns raised regarding lack of clinical trials and standard treatment protocols for certain AYUSH formulations;
- (b) if so, the steps taken to ensure transparency and scientific validation;
- (c) whether any timelines have been fixed for publishing peer-reviewed evidence;
- (d) whether Government proposes to integrate AYUSH services in district hospitals and Primary Health Centres;
- (e) if so, the present coverage of such service, State-wise; and
- (f) the budgetary allocation made for the same during the last three years?

ANSWER

THE MINISTER OF STATE (IC) OF THE MINISTRY OF AYUSH
(SHRI PRATAPRAO JADHAV)

- (a) to (f) A statement is laid on the Table of the House.

THE STATEMENT REFERRED TO IN REPLY TO LOK SABHA STARRED QUESTION NO. 110 FOR 10TH FEBRUARY 2026

(a) and (b) For issue of license to manufacture for sale of the Ayurveda, Siddha, Sowa-Rigpa and Unani medicines, the conditions relating to safety study and experience or evidence of effectiveness has been provided under Rule 158B of Drugs Rules, 1945. As per Rule 168 of Drugs Rules 1945, manufacturer has to comply standards for manufacturing of Ayurveda, Siddha and Unani drugs. Further Rule 85 (A to I) of the Drugs Rules, 1945 provides the regulatory guidelines for issue of license to manufacture Homoeopathy medicines, wherein for license to new homoeopathy medicines, the manufacturer shall produce such documentary and other evidence as may be required by licensing authority for accessing the therapeutic efficacy of the medicines including minimum proving carried out with it. Second Schedule (4A) of the Drugs and Cosmetics Act, 1940 provides for quality standards of Homoeopathic drugs.

Clinical trials are carried out by adopting prevalent guidelines such as Good Clinical Practice Guidelines for ASU drugs (GCP-ASU), Ethical guidelines for Bio-Medical Research (ICMR), and WHO guidelines for traditional medicines, etc., as per requirement. Further an addendum to ICMR National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017 for research in integrative medicine has also been published in year 2025.

Ministry of Ayush is implementing the Central Sector Scheme, namely Ayurgyan Scheme. The Scheme inter-alia has the components of (i) Research & Innovation in Ayush and ii) Ayurveda Biology Integrated Health Research. Under the Research & Innovation in Ayush and Ayurveda Biology Integrated Health Research components, financial assistance has been provided to the Organizations/Institutions for research studies including clinical research in Ayush systems of medicines. Number of Publications of the Research Activities conducted on Ayush formulations under the component of Research & Innovation in Ayush of Ayurgyan Scheme during the period from FY 2022-23 to 2025-26 are available at **Annexure I**.

Further, Government of India has established Central Council for Research in Ayurvedic Sciences, Central Council for Research in Unani Medicine, Central Council for Research in Homoeopathy, Central Council for Research in Siddha and Central Council for Research in Yoga & Naturopathy under the Ministry of Ayush as apex organizations for undertaking, coordinating, formulating, developing and promoting research in Ayush system on scientific lines. Core Research activities comprise of Medicinal Plant Research (Medico-

Ethno Botanical Survey, Pharmacognosy and cultivation), Drug Standardization, Pharmacological Research, Clinical Research, Literary Research & Documentation and Tribal Health Care Research Programme. Research activities are carried out through its peripheral Institutes/Units located across the country and also in collaboration with various Universities, Hospitals and Institutes. The details of clinical evidence on Ayush formulations published by research councils under Ministry of Ayush, during the last three years are available at **Annexure II.**

The Central Council for Research in Ayurvedic Sciences is also conducting scientific validation of new combinations (coded drugs) through systematic process of drug development viz. drug standardization and quality control, preclinical safety/toxicity studies and biological activity studies (as appropriate) and clinical trials as per requirement.

Standard Treatment Guidelines (STGs) for Ayurveda, Unani, Siddha, and Homeopathy with Yoga integration have been published for the following diseases:

- A. Standard Treatment Guidelines on Management of Common Musculoskeletal Disorders, published in year 2024 includes STGs on Osteoarthritis, Rheumatoid arthritis, Cervical spondylosis, Lumbar spondylosis, Fibromyalgia, Adhesive capsulitis
- B. Standard Treatment Guidelines on Management of Metabolic disorders, published in year 2025 includes STGs on Diabetes Mellitus, Dyslipidemia, Gout, Non-Alcoholic Fatty Liver Disease and Obesity.

(c) Research outputs are published upon completion of studies and after the requisite processes of data analysis, peer review, and compliance with ethical and regulatory standards. Research projects conducted under various councils and National Institutes follow their respective study timelines. Findings from completed clinical studies are submitted to peer-reviewed journals in accordance with established scientific practice.

(d) and (e) Government of India has adopted a strategy of Co-location of Ayush facilities at Primary Health Centers (PHCs), Community Health Centers (CHCs) and District Hospitals (DHs), thus enabling choice to the patients for different systems of medicines under single window. The engagement of Ayush Doctors/paramedics and their training is supported by the Ministry of Health & Family Welfare under National Health Mission (NHM), while the support for Ayush infrastructure, equipment /furniture and medicines is provided by Ministry of Ayush under National Ayush Mission (NAM) as shared responsibilities.

`Ayush services have been co-located at 13,094 health facilities (472 DHs, 3133 CHCs, 246 Other than CHCs at or above block level but below district level, 6206 PHCs and 3037 Other health facilities above Sub Centre but below block level) as on 30th June 2025. State-wise status is available at **Annexure-III**.

(f) Under NAM, status of grant-in-aid released for different activities including Ayush services at co-located facilities during last three years is available at **Annexure -IV**.

Annexure I

Number of Publications of the Research Activities conducted on Ayush formulations under the component of Research & Innovation in Ayush of Ayurgyan Scheme during the period from FY 2022-23 to 2025-26 are as follows: -

S. No.	System	Number of Publications
1.	Ayurveda	12
2.	Siddha	08
3.	Unani	08
4.	Homoeopathy	06

Annexure II

The details of clinical evidence on Ayush formulations published by research councils under Ministry of Ayush, during the last three years are as follows-

S. No.	System	No. of clinical evidence published in last three years
1.	Ayurveda	72
2.	Siddha	27
3.	Unani	115
4.	Homoeopathy	156

Annexure-III.

State-UT wise status of present coverage of co-located facilities is as follows: -

State	DH	CHC	Other than CHC (below district)	PHC	Other health facilities (above SC, below block)	Total
Andaman & Nicobar Islands	3	4	0	20	0	27
Andhra Pradesh	9	105	0	273	0	387
Arunachal Pradesh	16	34	0	50	5	105
Assam	18	7	4	71	500	600
Bihar	36	0	0	0	1348	1384
Chandigarh	1	2	2	33	0	38
Chhattisgarh	18	98	0	454	0	570
Dadra & Nagar Haveli & Daman & Diu	2	1	1	14	1	19
Delhi	0	0	0	0	208	208
Goa	2	6	2	22	1	33
Gujarat	0	0	0	868	0	868
Haryana	22	102	0	106	5	235
Himachal Pradesh	0	0	0	0	0	0
Jammu & Kashmir	13	14	0	373	571	971
Jharkhand	21	188	0	97	225	531
Karnataka	20	190	139	163	0	512
Kerala	0	0	0	0	0	0
Ladakh	2	7	0	32	0	41
Lakshadweep	2	3	2	4	0	11
Madhya Pradesh	36	95	0	275	0	406
Maharashtra	23	238	0	20	0	281

Manipur	7	17	1	85	0	110
Meghalaya	11	25	0	54	0	90
Mizoram	12	9	1	10	38	70
Nagaland	9	20	0	9	0	38
Odisha	0	351	0	886	0	1237
Puducherry	4	4	0	39	0	47
Punjab	22	66	18	87	8	201
Rajasthan	2	56	4	128	1	191
Sikkim	4	1	0	4	0	9
Tamil Nadu	37	388	0	475	0	900
Telangana	0	42	0	352	0	394
Tripura	3	21	11	84	0	119
Uttar Pradesh	91	691	0	687	31	1500
Uttarakhand	13	53	7	44	0	117
West Bengal	13	295	54	387	95	844
Total	472	3133	246	6206	3037	13094

Annexure-IV

Status of grant-in-aid released for different activities including Ayush services at co-located facilities during last three years under NAM is as follows: -

S. No.	Year	Amount Released as Central Share
1	2022-23	Rs. 547.49 crore
2	2023-24	Rs. 867.33 crore
3	2024-25	Rs. 1136.54 crore
Total		Rs. 2,551.36 crore
