GOVERNMENT OF INDIA MINISTRY OF AYUSH

RAJYA SABHA

UNSTARRED QUESTION No. 166 TO BE ANSWERED ON 04.02.2025

Research in AYUSH System of medicines

166 Dr. M. Thambidurai:

Will the Minister of AYUSH be pleased to state:

- (a) whether it is a fact that the Government encourages research in AYUSH system of medicines;
- (b) if so, the details thereof;
- (c) the details of funds allocated/utilised for the research in AYUSH System of Medicine during the last five years, year-wise;
- (d) whether the Government has studied the quality of AYUSH medicines, separately;
- (e) if so, the details thereof, including the need to improve the quality of AYUSH medicines; and
- (f) the steps taken by Government to improve the quality of AYUSH medicines?

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

- (a) & (b): Yes, As per Allocation of Business Rules, Ministry of Ayush has a mandate for coordination and promotion of research and development including assistance therefor in Ayush Systems of Health Care. Ministry has five Autonomous Organisations working under it having a common objective of Evidence Based Research in their respective systems of medicine. These five Research Councils are:
- (1) Central Council for Research in Ayurvedic Sciences (CCRAS)
- (2) Central Council for Research in Yoga and Naturopathy (CCRYN)
- (3) Central Council for Research in Unani Medicine (CCRUM)
- (4) Central Council for Research in Siddha (CCRS)
- (5) Central Council for Research in Homoeopathy (CCRH)

Research Councils are the apex bodies in their respective field in India for undertaking, coordinating, formulating, developing, and promoting research on scientific lines in their respective fields. These Councils carry out their research activities through their peripheral institutes located all over India and also through their collaborative studies with various Universities, Hospitals and Institutes. The main activities of these Councils comprise Clinical Research, Drugs Standardization Research & Quality Control, Pharmacology Research, Literary Research, Fundamental Research, Survey & Cultivation of Medicinal Plants & Research oriented Public Healthcare Programmes etc.

Ministry of Ayush is implementing an umbrella Central Sector Scheme namely "AYURGYAN" from the FY 2021-22 with the aim to support Research & Innovation in Ayush by providing Extra Mural Research activities and Education by providing academic activities, training, Capacity Building etc. The Scheme has three components, viz. (i) Capacity Building and Continuing Medical Education (CME) in Ayush, (ii) Research & Innovation in Ayush from FY 2021-22 and (iii) Ayurveda Biology Integrated Health Research is also added under the scheme from FY 2023-24. The scheme is approved upto FY 2025-26.

Further, Ministry of Ayush is running an umbrella scheme, namely, "AYURSWASTHYA Yojana" from the FY 2021-22 which was developed by merging two earlier schemes of this Ministry i.e. (i) Central Sector Scheme of Grant-in-aid for promotion of Ayush intervention Public Health Initiatives; and (ii) Central Sector Scheme for assistance to Ayush Organisations (Government/ Non-Government Non-Profit) engaged in AYUSH Education/ Drug Development & Research/ Clinical Research etc. for upgradation to Centre of Excellence (CoE). This Scheme has been approved upto FY 2025-26. The components of the AYURSWASTHYA Yojana are mentioned below:

- (1) AYUSH and Public Health (PHI)
- (2) Centre of Excellence (CoE)

The National Commission for Indian Systems of Medicine (NCISM) and the Nation Commission for Homoeopathy (NCH) have notified their respective Ayush Graduate Degree Courses regulations wherein Research Methodology subject is introduced at undergraduate level to promote young researchers. For each department in Indian Systems of Medicine and Homoeopathy Medical Colleges, methodology for supplementing modern advancement, research and technology in Indian Systems of Medicine and Homoeopathy are included in regulations. The Commissions have conducted research methodology training for post graduate students and teachers in association with scientists of respective Research Councils of the Ayush System of Medicine.

(c): Ministry of Ayush allocates funds to the five Research Councils. The funds are utilised on various items including research since there is no dedicated head for research. Details of allocations made under Budget Estimates are at **Annexure**.

(d) to (f): The Drugs & Cosmetics Act, 1940 and Drugs Rules, 1945 have exclusive regulatory provisions for Ayurvedic, Siddha, Unani, and Homoeopathy drugs. Rule 158-B in the Drugs Rules, 1945 provides the regulatory guidelines for issue of license to manufacture Ayurvedic, Siddha, Unani medicines and Rule 85 (A to I) in the Drugs and Cosmetics Rules, 1945 provides the regulatory guidelines for issue of license to manufacture Homoeopathy medicines.

Ministry of Ayush has established Pharmacopoeia Commission for Indian Medicine & Homoeopathy (PCIM&H) to lay down the Formulary specifications and Pharmacopoeial Standards for ASU&H drugs, which serve as official compendia for ascertaining the Quality Control (identity, purity and strength) of ASU&H drugs included herein, as per Drugs & Cosmetics Act, 1940 and Rules, 1945, thereunder and compliance of these quality standards are mandatory for the production of ASU&H drugs, to sell and stock in India. The quality parameters included in the Pharmacopoeias and Formularies of ASU&H drugs, prescribing mandatory regulatory standards, have been identified to align the parameters prescribed by WHO/other major Pharmacopoeias prevalent worldwide.

So far, 2259 quality standards on raw materials (Single Drugs of plant/animal/Mineral/Metal/Chemical origin) used in ASU&H have been published. Also, 405 quality standards of ASU formulations also been published in respective Pharmacopoeias. Further, 2799 formulary specifications of ASU drugs also published in Formularies of respective system.

In addition to above, supporting documents in the form of Macro-Microscopic & TLC Atlas on 351 single drugs incorporated in API also published. PCIM&H also acts as an appellate drug testing laboratory receives the samples from Government agencies as per Drugs & Cosmetics Act & Rules thereunder for ascertaining their quality.

Further, PCIM&H also impart training to the Drug Regulatory Authorities, State Drug Testing Laboratories (Drug Analysts) etc. on laboratory techniques and methods used to maintain the quality of ASU&H drugs. During the last five years, 15 training programmes were conducted by PCIM&H.

Pharmacovigilance Program for Ayurveda, Siddha, Unani, and Homoeopathy (ASU&H) Drugs has been established under the Central Sector Scheme of Ministry of Ayush (AOGUSY Scheme). A three tier structure functional since 2018 comprising of a National Pharmacovigilance Co-ordination Centre (NPvCC), Five Intermediary Pharmacovigilance Centres (IPvCs) and Ninety-nine Peripheral Pharmacovigilance Centres (PPvCs) is 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. The vision of the program is to improve patient safety in Indian population by monitoring the drug safety in ASU&H drugs by inculcating the reporting culture of Suspected Adverse Drug

Reactions, keeping surveillance of misleading advertisements appearing in print and electronic media also the awareness events are being regularly organized across the country to generate awareness regarding the Ayush therapeutic approaches and educate about the systematic use of Ayush drugs in healthcare professionals.

Annexure

Statement showing the details of the funds allocated/ utilised in respect of Research Councils during the last 5 years

SI.	Research	2019-20		2020-21		2021-22		2022-23		2023-2024		
No.	Institute						(Rs. In crores)					
		B.E.	Actual	B.E.	Actual	B.E.	Actual	B.E.	Actual	B.E.	Actual	
			Expdr.		Expdr.		Expdr.		Expdr.		Expdr.	
1.	CCRAS	292.31	280.68	297.00	264.16	328.27	312.72	358.50	354.40	379.50	394.89	
2.	CCRUM	152.65	159.54	157.00	164.05	167.79	157.73	175.80	173.42	173.30	174.10	
3.	CCRH	118.53	128.83	138.50	130.50	167.58	135.33	143.70	143.70	145.00	140.25	
4.	CCRYN	41.35	61.71	40.50	48.30	59.70	57.44	85.24	42.62	103.57	43.04	
5.	CCRS	36.50	33.00	35.00	35.30	36.77	39.06	46.67	46.88	51.36	50.91	