GOVERNMENT OF INDIA
MINISTRY OF AYUSH

LOK SABHA
UNSTARRED QUESTION NO. 1318
TO BE ANSWERED ON 09th February, 2024

"Production and Distribution of AYUSH Medicines"

1318. DR. NISHIKANT DUBEY:
SHRIMATI POONAMBEN MAADAM:
SHRI KHAGEN MURMU:
SHRI HARISH DWIVEDI:
DR. (PROF.) KIRIT PREMJIBHAI SOLANKI:
SHRI PRADEEP KUMAR SINGH:
SHRIMATI SANDHYA RAY:
SHRI RATANSINH MAGANSINH RATHOD:
SHRI P.C. MOHAN:
DR. RAM SHANKAR KATHERIA:

(a) whether the Government has taken steps for the qualitative production and distribution of AYUSH medicines;
(b) if so, the details thereof;
(c) whether the Government proposes to widen and deepen the research into AYUSH medicines; and
(d) if so, the details thereof?

ANSWER
THE MINISTER OF AYUSH
(SHRI SARBANANDA SONOWAL)

(a) and (b) Yes. Government has taken following steps for the qualitative production and distribution of AYUSH medicines:

i. 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, Unani and Homoeopathy drugs, is vested with the State Drug

Controllers/ State Licensing Authorities appointed by the concerned State/ Union Territory Government. Rule 158-B in the Drugs and Cosmetics 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. 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.

ii. In 2021, Ministry of Ayush has implemented Central Sector Scheme AYUSH Oushadhi Gunvatta 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 centres.

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

iii. Government of India has established Pharmacopoeia Commission for Indian Medicine & Homoeopathy (PCIM&H), as its subordinate office. PCIM&H on behalf of Ministry of Ayush lays down the formulary specifications and Pharmacopoeial Standards for Ayurveda, Siddha, Unani and Homoeopathy (ASU&H) drugs/ medicines, which serve as official compendia for ascertaining the quality control (identity, purity and strength) of the ASU&H drugs, included herein, as per Drugs & Cosmetics Act, 1940 and Rules 1945, thereunder and compliance to these quality standards are mandatory for the production of ASU&H drug

being manufactured in India. Implementation of these pharmacopoeial standards ensures that the medicines reaching to masses conform to optimum quality standards in terms of identity, purity and strength. So far, 2259 quality standards on raw materials (single drugs of plant/ animal/ Mineral/ metal/ chemical origin) used in ASU&H has been published. Further, 405 quality standards and 2666 formulary specifications of Ayurveda, Siddha, Unani (ASU) formulations have also been published in respective pharmacopoeia.

In addition to above, supporting documents in the form of Macro-Microscopic & TLC Atlas on 351 single drugs incorporated in Ayurvedic Pharmacopoeia of India (API) has also been published. PCIM&H act as an appellate drug testing laboratory and receives samples from Government agencies as per Drugs & Cosmetics Act, 1940 & Rules there under for ascertaining their quality. PCIM&H on behalf of Ministry of Ayush, also imparts 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.

iv. Government has established Indian Medicines Pharmaceutical Corporation Limited (IMPCL) in the year 1978 which is manufacturing and supplying Ayurveda and Unani medicines in the country.

v. Rule 160 A to J of the Drugs and Cosmetics Rules, 1945 provides the regulatory guidelines for approval of Drug Testing Laboratory for carrying out such tests of identity, purity, quality and strength of Ayurvedic, Siddha and Unani drugs as may be required under the provisions of these rules, on behalf of licensee for manufacture of Ayurvedic, Siddha and Unani drugs. As on date, 34 State Drug Testing Laboratories have been supported for strengthening their infrastructural and functional capacity. Further, 106 laboratories are approved or licensed under the provisions of Drugs and Cosmetics Rules, 1945 for quality testing of Ayurvedic, Siddha and Unani drugs and raw materials. Details of the State Drug Testing Laboratories and Private Drug testing laboratories licensed under the provisions of Drugs and Cosmetics Rules, 1945 are available at https://ayush.gov.in/images/domains/quality_standards/StateDrugTestingLaboratoryASUHEng. and https://ayush.gov.in/images/domains/quality_standards/ListofAyurvedaSiddhaUnani.pdf.

vi. In 2009, Quality Control of India (QCI), at the behest of the then Department of AYUSH (Now Ministry of Ayush), launched a voluntary certification scheme for Ayush Products

having two levels – AYUSH Standard Mark and AYUSH Premium Mark. Currently there are 5435 products carrying AYUSH Mark. Details of the schemes are available at https://padd.qci.org.in/voluntary-certification-scheme-for-ayush-products/.

vii. Central Drugs Standard Control Organization (CDSCO) issues the Certificate of Pharmaceutical Product (COPP) of Ayurvedic products for export purpose based on joint inspection by representatives from CDSCO, Ministry of Ayush and respective State Licensing Authority. Details are available at https://cdsco.gov.in/opencms/opencms/en/Aayush/.

(c) and (d) Government of India has established Central Council for Research in Ayurvedic Sciences (CCRAS), Central Council for Research in Unani Medicine (CCRUM), Central Council for Research in Homeopathy (CCRH), Central Council for Research in Siddha (CCRS) and Central Council for Research in Yoga & Naturopathy (CCRYN) 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, 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.

To widen and deepen the research into Ayush medicines, Institute of Teaching and Research in Ayurveda (ITRA), Jamnagar has recently made a MoU with Gujarat Biotechnology Research Center (GBRC), Gandhinagar and IIT, Gandhinagar.

National Institute of Homoeopathy (NIH) has taken initiative to collaborate with National Institute of Pharmaceutical Education & Research (NIPER) at Kolkata and the title of the project is "Evaluation of Homoeopathic Preparation and its potency as potential therapy for Inflammatory Bowel Disease".

National Commission for Homoeopathy is constituted on 5th July 2021 to standardize homoeopathy education and homoeopathy practice in India. Various steps taken by Homoeopathy Education Board of National Commission for Homoeopathy to promote education, research and innovation are at **Annexure-I.**

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Annexure-I

Steps taken by Homoeopathy Education Board of National Commission for Homoeopathy to promote education, research and innovation are as follows –

- National Commission for Homoeopathy encourages Homoeopathy Medical professionals to adopt latest medical research in their work and contribute to research in Homoeopathy.
- National Commission for Homoeopathy has notified the Homoeopathy Graduate Degree Course-B.H.M.S regulation on 07.12.22 wherein Research Methodology subject is introduced at undergraduate level to promote young researchers.
- For each department in Homoeopathy Medical College, methodology for supplementing modern advancement, research and technology in homoeopathy (SMART-Hom) is included in regulation.
- It has been recommended to have research journals subscription and research library in Homoeopathy medical colleges to motivate the faculty and students for conducting research.
- Homoeopathy medical colleges are guided to maintain systematic documentation of cases being treated at attached hospitals for proper analysis and for undertaking future research.
- Regulation for Research in Homoeopathy Gazette notified on 04.12.2023.
- Total 03 stakeholders meet are conducted by NCH during 2022-23 wherein education matter and research were discussed at length.
- Online training program was conducted to encourage & enlighten the clinical research methods knowledge of the postgraduate students in view of synopsis and dissertation.
- Training conducted with participation of about 2300 PG students and approx. 600 PG faculties from 60 PG colleges all over India.