GOVERNMENT OF INDIA
MINISTRY OF AYUSH

RAJYA SABHA
UNSTARRED QUESTION NO.1045
TO BE ANSWERED ON 7TH DECEMBER, 2021

ACTION PLAN TO STANDARDISE PRODUCT OF AYUSH AND ITS MANUFACTURING PROCESS

1045. MS. SAROJPANDEY:

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

a) whethergovernment has formulated any action-plan to standardize the products of AYUSH and its manufacturing practices and to evolve the research in the said area, if so, the number of AYUSH products and intellectual property rights based products which have been produced under the said action-plan during the last five years to the present?

ANSWER
THE MINISTER OF AYUSH
(SHRI SARBANANDA SONOWAL)

(a) Yes Sir, for standardization of Ayurvedic, Siddha, Unani and Homoeopathy (ASU&H) medicines in the country, the Government has established Pharmacopoeia Commission for Indian Medicine and Homoeopathy(PCIM&H) under the Ministry of AYUSH. The prime mandate of the Commission is to publish and revise Ayurvedic Pharmacopoeia of India (API), Siddha Pharmacopoeia of India (SPI), Unani Pharmacopoeia of India (UPI) and Homoeopathic Pharmacopoeia of India (HPI). The Pharmacopoeial standards are basic need to ensure quality, safety and efficacy of Ayurvedic, Siddha, Unani and Homoeopathic medicines. The Pharmacopoeia Commission is also responsible to publish and revise Ayurvedic, Siddha and Unani official formularies and regulatory compendiums. These published standards become part of Drugs and Cosmetics Act, 1940 and Rules, 1945 for ascertaining the quality standards of Raw materials/drugs and implemented uniformly across India.

It is mandatory for the manufacturer of ASU&H drugs to obtain licence from the concerned State Licensing Authority (SLA) and comply with the prescribed Good Manufacturing Practices (GMP) and quality standards of drugs given in the respective Pharmacopoeias. The SLA grants the licence after verification of the required infrastructural facilities, equipment / machinery, manpower of the manufacturing unit through inspection(s) conducted by the inspector.

Government has also set up separate Central Research Councils for undertaking, promoting, coordinating research and scientific validation of Ayurvedic, Unani, Siddha and Homoeopathic medicines.

So far Government has published Ayurvedic Formulary of India (Part I-III) containing 986 Formulations, Siddha Formulary of India (Part I-II) containing 400 Formulations and National Formulary of Unani Medicine (Vol. I-VI) containing 1230 Formulations. Monographs of quality standards of 645 Single drugs and 203 Formulations of Ayurveda; 139 Single drugs and 1 Formulation of Siddha; 298 Single drugs and 201 Formulations of Unani; and 1117 drugs of Homoeopathy (Vol. I-X).The Central Council for Research in Homoeopathy (CCRH) has filed 8 patents and the Central Council for Research in Ayurvedic Sciences (CCRAS) has obtained one patent, the Central Council for Research in Siddha (CCRS) has processed for patent of 10 products during last five years.

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