**GOVERNMENT OF INDIA**
**MINISTRY OF AYUSH**

**LOK SABHA**
**UNSTARRED QUESTION NO.2095**
**TO BE ANSWERED ON 10TH DECEMBER, 2021**

**QUALITY CONTROL AND STANDARIDISATION OF AYURVEDIC PRODUCTS**

**2095. SHRI VISHNU DATT SHARMA:**

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

(a) whether the Government is making efforts to ensure quality control and standardisation of ayurvedic products and scientific validation of Ayurvedic principles using modern guidelines to make it more acceptable to consumers.
(b) if so, the details of measures taken in this regard; and
(c) If not, the reasons therefor?

**ANSWER**
**THE MINISTER OF AYUSH**
**(SHRI SARBANANDA SONOWAL)**

(a) to (b)Yes Sir, the Drugs and Cosmetics Act 1940 and rules made thereunder specifies procedure for granting license to manufacture, inspection of premises, permission for sale, Inspection, examination, audit, display requirement, registers, records, return filing & statutory reporting, Good Manufacturing Practice (GMP), online submission(through portal 'e-aushadhi.gov.in') and processing of application for licensing of AYUSH drugs and related matters for ensuring quality, safety and efficacy of AYUSH medicines.

For standardization of Ayurvedic, Siddha, Unani and Homoeopathy (ASU&H) medicines in the country, the Government has established a central drug laboratory, namely '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).

(c) Does not arise.