**GOVERNMENT OF INDIA**

**MINISTRY OF AYUSH**

**RAJYA SABHA**

**UNSTARRED QUESTION NO. 1927**

**TO BE ANSWERED ON 18.03.2025**

**MoU between India and Indonesia in the field of traditional medicine**

1927 **Dr. Sikander Kumar:**
**Smt. Sunetra Ajit Pawar:**

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

(a) whether India and Indonesia have exchanged Memorandum of Understanding in the field of traditional medicine;
(b) if so, the details thereof;
(c) whether this partnership will preserve and innovate within their rich medicinal traditions, contributing to the growing recognition and acceptance of traditional medicine globally, if so, the efforts taken in this regard; and
(d) whether Government is taking any innovative steps to ensure the safety, efficacy and quality of traditional medicines, setting the stage for a more integrated and scientifically – regulated approach to this valuable healthcare system?

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

(a) Yes Madam/ Sir. The Memorandum of Understanding (MoU) is signed between Indonesian Food and Drug Authority of the Republic of Indonesia and Pharmacopoeia Commission for Indian Medicine & Homoeopathy (PCIM&H), Ministry of Ayush of the Republic of India on cooperation in the field of traditional medicine quality assurance.

(b) & (c) Each country will endeavor to take necessary steps to encourage and promote co-operation in the following forms:

- Exchange of information, experience and knowledge regarding the regulatory provisions for traditional medicine;

- Exchange of experts for capacity building activities including seminars, workshops and training;
- Technical visit related to familiarization of regulatory processes of both Countries;
- Participation in international events organized by either country;
- Joint training programmes in mutually agreed areas, either for the Countries or related industries, as agreed by the countries; and

Any other forms of co-operation, as agreed by the Countries.

(d) 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 provide the regulatory guidelines for issuing license to manufacture Ayurvedic, Siddha, Unani medicines and Rule 85 (A to I) in the Drugs Rules, 1945 provides the regulatory guidelines for issuing license to manufacture Homoeopathy medicines. lt 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-l of Drugs Rules, 1945 and quality standards of drugs given in the respective pharmacopoeia.

Ministry of Ayush, 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 which serves as official compendia for ascertaining the quality (identity, purity and strength) of the ASU&H drugs. As per the Drugs & Cosmetics Act, 1940 and rules there under, the compliance to this quality standards are mandatory for the production of ASU&H drugs being manufactured in India. Pharmacovigilance Program for Ayurveda, Siddha, Unani, and Homoeopathy (ASU & H) Drugs has been established under Ayush Oushadhi Gunvatta Evam Uttpadan Samvardhan Yojana (AOGUSY Scheme), a Central Sector Scheme of Ministry of Ayush.

A three-tier structure functional since 2018 comprising of a National Pharmacovigilance Coordination 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 ASU&H 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.

****