GOVERNMENT OF INDIA
MINISTRY OF AYURVEDA, YOGA & NATUROPATHY,
UNANI, SIDDHA AND HOMOEOPATHY
(AYUSH)

LOK SABHA
UNSTARRED QUESTION NO. 3286
TO BE ANSWERED ON 4TH AUGUST, 2017

GRADING SYSTEM FOR PRODUCTS

3286. SHRI RAM MOHAN NAIDU KINJARAPU:

Will the Minister of **AYURVEDA, YOGA AND NATUROPATHY, UNANI, SIDDHA AND HOMOEOPATHY (AYUSH)** be pleased to state:

(a) whether there is grading systems for products which fall under the Indian system of medicine and Homoeopathy and if so, the details thereof;

(b) whether there are differences between the grading and standardisation of products from Indian Systems of Medicine and Homoeopathy (ISMH) and for those of practices which come under allopathy and if so, the details thereof;

(c) whether any incidents have been reported to the Ministry which could have risen from non-grading or standardisation of products of AYUSH and if so, the details thereof;

(d) whether the Government proposes to introduce legislation in this regard in the future; and

(e) if so, the details thereof?

ANSWER
THE MINISTER OF STATE (IC) OF THE MINISTRY OF AYURVEDA, YOGA & NATUROPATHY, UNANI, SIDDHA AND HOMOEOPATHY
(SHRI SHRIPAD YESSO NAIK)

(a): Under the provisions of Drugs & Cosmetics Rules, 1945, Good Manufacturing Practices and Quality standards prescribed in the respective pharmacopoeias are mandatory for the manufacturing of licensed Ayurvedic, Siddha, Unani and Homoeopathic medicines. In addition, two voluntary certification schemes for Ayurvedic, Siddha and Unani medicines are implemented respectively by the Quality Council of India for grant of AYUSH Standard & AYUSH Premium marks and quality certification of products as per WHO-GMP and COPP guidelines by the Central Drugs Standard Control Organization (CDSCO).

(b): Ayurvedic, Siddha, Unani and Homoeopathic drugs are regulated in accordance with the exclusive provisions for them in the Drugs & Cosmetics Act, 1940 and Rules thereunder. These drugs have to adhere to such standards and quality control parameters as given in the authoritative books, pharmacopoeias and formularies of Ayurvedic, Siddha,

Contd…….

Unani and Homoeopathic systems, which are different from that prescribed for allopathic medicines. Till date, monographs of quality standards of 645 single drugs & 202 compound formulations of Ayurveda, 298 single drugs & 150 compound formulations of Unani system, 139 single drugs of Siddha and 1117 monographs of Homoeopathic drugs have been published in the respective pharmacopoeias. Similarly, Ayurvedic Formulary contains 985 standardized formulations, Unani Formulary 1229 formulations and Siddha Formulary has 399 standardised formulations.

(c): Appellate Laboratories for Indian Medicine and Homoeopathy under the provisions of Drugs & Cosmetics Rules, 1945 have reported testing of referred samples of Ayurvedic, Siddha, Unani and Homoeopathy drugs during last three years as under-

Year	**Pharmacopoeial Laboratory of Indian Medicine**		**Homoeopathic Pharmacopoeial Laboratory**	
	Samples tested	**Samples failed**	**Samples tested**	**Samples failed**
2014-15	11	04	401	142
2015-16	25	01	351	150
2016-17	37	01	387	49

The Appellate Laboratories after testing of the referred samples send the analysis reports to the concerned authority for necessary action. Regulation and Quality control of Ayurvedic, Siddha, Unani and Homoeopathic medicines is carried out by the State Licensing Authorities / Drug Controllers. As per the information made available from the States, 11889 samples of AYUSH medicines have been tested in 24 States during the last three years from 2013-14 to 2015-16 out of which 254 samples failed in quality testing. State Licensing Authorities reported to have initiated appropriate actions against the samples not complying with the standards including issue of show cause notice, suspension /cancellation of license, recall of the concerned batch of medicines from the market and prosecution.

(d): & (e): Exclusive regulatory provisions for licensing, standards and quality control of Ayurvedic, Siddha, Unani and Homoeopathic medicines exist in the Drugs & Cosmetics Act, 1940 and Rules thereunder. Drugs and Cosmetics Rules, 1945 are amended on the recommendations of the respective Drugs Technical Advisory Board for imposing effective quality control provisions following the stipulated procedure of consultation with the stakeholders and approval of the competent authorities. As of now there is no proposal in the Ministry of AYUSH to introduce new legislation for grading and standardization of AYUSH products.

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