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

LOK SABHA
STARRED QUESTION NO. 324
TO BE ANSWERED ON THE 24th March, 2017

AYURVEDIC MANUFACTURING UNITS

***324. DR. RAMESH POKHRIYAL "NISHANK":**

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

(a) the mechanism in place to monitor the quality of Ayurvedic medicines;

(b) whether the efforts are to introduce Good Laboratory Practice (GLP)/Good Manufacturing Practice (GMP) Ayurvedic medicine in manufacturing units on the lines of Allopathy medicines and if so, the details thereof;

(c) whether steps have been taken to improve the quality of Ayurvedic medicines and other AYUSH products and if so, the details thereof; and

(d) whether steps have also been taken to prevent the use of heavy metals and other harmful elements in Ayurvedic medicines and AYUSH products and 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) to (d): A statement is laid on the Table of the House.

STATEMENT REFERRED TO IN REPLY TO LOK SABHA

STARRED QUESTION NO. 324 FOR 24th March, 2017

(a) The regulatory and quality control mechanism *inter-alia* for Ayurvedic medicines has been established in the country in accordance with the provisions of the Drugs & Cosmetics Act, 1940 and rules thereunder which are amended from time to time. Exclusive provisions exist in the Drugs & Cosmetics Act, 1940 and rules thereunder for the licensing, manufacturing, labeling, shelf-life and testing of these drugs. State Governments are responsible to enforce the legal provisions for Ayurvedic medicines, for which Licensing Authorities/Drug Controllers are appointed in the states. Good Manufacturing Practices and Quality Standards for manufacturing of Ayurvedic medicines as prescribed in the Drugs & Cosmetics Rules, 1945 and the Ayurvedic pharmacopoeia, respectively are mandatory for the manufacturers to follow. Quality and authenticity of the Ayurvedic medicines is checked on the basis of standards of identity, purity and strength prescribed in the pharmacopoeia. For this purpose Central Government has set up Pharmacopoieal Laboratory of Indian Medicine in Ghaziabad, Uttar Pradesh as an appellate laboratory and there are 27 State Drugs Testing Laboratories and 44 laboratories approved under the provisions of Drugs & Cosmetics Rules, 1945 for testing of Ayurvedic medicines and raw materials. States have appointed inspectors to inspect the Ayurvedic manufacturing units and take samples for testing or analysis. Guidelines for issue of license for the manufacturing of various categories of Ayurvedic medicines are prescribed under Rule 158-B of the Drugs & Cosmetics Rules, 1945 including the requirement of submission of proof of safety and effectiveness of the drug applied for obtaining manufacturing license from the Licensing Authority.

(b) Provisions for Good Manufacturing Practices (GMP) and Laboratory Practices with regard to manufacturing and quality testing of Ayurvedic medicines are prescribed in the Drugs & Cosmetics Rules, 1945 since 2003. These provisions describe the requirements of premises and distribution of space, equipment & machinery, manpower, reference materials, record keeping, standard operating procedures, etc.. System for certification of GMP compliance and quality of pharmaceutical products as per the WHO guidelines is applicable to Ayurvedic medicines on voluntary basis,which is administered under the aegis of the Drug Controller General (India) [DCG (I)]. Joint inspection for this purpose is carried out by the representatives of the DCG (I), Ministry of AYUSH and the concerned

State Licensing Authority. NABL accreditation is also available for laboratories of Ayurvedic medicines on voluntary basis.

(c) Following steps have been taken to improve the quality of Ayurvedic medicines and other AYUSH products:

1. Pharmacopoeial Commission of Indian Medicine and Homoeopathy (PCIM&H) and Pharmacopoeia Committees have been set up to develop the standards and the Standard Operating Procedures of Ayurvedic, Siddha, Unani and Homoeopathic medicines.

2. Quality standards of 847 Ayurvedic drugs, 139 Siddha drugs, 448 Unani drugs and 1117 Homoeopathic drugs have been developed and published in the respective pharmacopoeias. Permissible limits of heavy metals, pesticide residue, aflatoxins and microbial load are also prescribed.

3. Standardized formulations (985 formulations of Ayurveda, 399 of Siddha, and 1229 of Unani) along with their methods of manufacturing are published in the respective Formularies.

4. Guidelines of Good Manufacturing Practices (GMP) for Ayurvedic, Siddha, Unani and Homoeopathic medicines are inserted in the Drugs & Cosmetics Rules, 1945 and it is mandatory for licensing of ASU&H drug manufacturing units.

5. Rule 158-B inserted in the Drugs and Cosmetics Rules, 1945 to provide the guidelines for issue of license to manufacture Ayurvedic, Siddha and Unani medicines in accordance with the evidence of safety and effectiveness.

6. Schedule E (1) containing the list of potentially hazardous substances of Ayurvedic, Siddha and Unani systems has been notified under the Drugs and Cosmetics Rules, 1945 including the provision to display on the label ‘Caution’ for the use of the formulations containing such ingredients under the medical supervision.

7. Two Central Laboratories- Pharmacopoeial Laboratory of Indian Medicine and the Homoeopathic Pharmacopoeial Laboratory are established and notified as appellate laboratories under the provisions of the Dugs and Cosmetics Rules, 1945.

8. 27 State Drug Testing Laboratories in public sector and 44 Laboratories approved under the provisions of the Drugs and Cosmetics Rules, 1945 are in place for quality testing of ASU&H drugs and raw materials.

9. Financial support has been provided to 46 state pharmacies, 27 State Drug Testing Laboratories and 30 State Licensing Authorities for improving their infrastructural and functional capacities for manufacturing, testing and enforcement of the provisions related to ASU&H drugs.

10. Grant-in-aid is provided to the States and UTs under National AYUSH Mission (NAM) for augmenting quality control activities for ASU&H drugs, including strengthening of Pharmacies, Drug Testing Laboratories, enforcement framework and testing of drugs.

11. Documents of Evidence based safety of Ayurvedic medicines, Essential Drug Lists, Good Clinical Practices for conducting Clinical Trials on ASU medicines, and procedural guidelines for inspection of Drug Testing Laboratory have been published.

12. In order to promote safe use of AYUSH medicines, the Ministry of AYUSH has signed anMoU with the Advertising Standards Council of India (ASCI) to undertake monitoring of misleading advertisements appearing in the print and TV mediaand bring the defaulters to the notice of the Central Government and the State regulators for taking necessary action.

d). Minerals and metals form an integral part of specific category of Ayurvedic, Siddha and Unani formulations called ‘Rasaushadhies’. Such ingredients are used in the preparation of medicines after subjecting them to certain pharmaceutical processes including ‘shodhana (detoxification)’, ‘marana (incineration & calcination)’, and ‘amritikarana (qualitative improvement)’ to render them safe and therapeutically effective, with rational use. In this regard, Part-I, Volume-VII of

the Ayurvedic Pharmacopoeia of India mentions the quality standards of 21 minerals & metals for regulating the use of these ingredients in the manufacturing of Ayurvedic, Siddha and Unani drugs. Schedule–E (1) of the Drugs & Cosmetics Rules, 1945 contains the list of 69 potentially hazardous substances of plant, mineral and animal origin including heavy metals. As per Rule 161 of the Drugs & Cosmetics Rules, 1945, in case of formulations containing any of the Schedule-E (1) ingredients, it is mandatory for the manufacturer to display on the label 'Caution: to be taken under medical supervision' both in English and Hindi languages.

******