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

LOK SABHA
UNSTARRED QUESTION NO. 45
TO BE ANSWERED ON 15TH DECEMBER, 2017

GOOD MANUFACTURING PRACTICE

45. KUMARI SUSHMITA DEV:
SHRI ANURAG SINGH THAKUR:

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

(a) the number of drug manufacturers under AYUSH category at present in the country;

(b) the present status of compliance of Good Manufacturing Practice (GMP) by manufacturing units across all States in the country;

(c) whether non-compliance of GMP has been reported in various States particularly in Assam;

(d) if so, the details thereof and action taken/being taken by the Government against such companies in the States particularly in Assam; and

(e) the steps being taken by the Government to regulate quality and pricing of AYUSH medicines?

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

(a): There are 8667 licensed Ayurvedic, Siddha, Unani and Homoeopathy (ASU&H) drug manufactures in the country.

(b): 7488 ASU&H drug manufacturers are reported to be complying with the prescribed Good Manufacturing Practices (GMP).

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(c) & (d): Non-compliance of GMP by 1179 ASU&H drug manufacturers has been reported in 16 States including 12 Ayurvedic drug manufacturers in the State of Assam. State Governments are responsible to enforce the regulatory provisions for ASU&H drugs. The status of GMP compliance by the ASU&H drugs manufacturing units is periodically reviewed by the Ministry of AYUSH and the necessary directions are given to the concerned State Authorities to take action against the defaulters in accordance with the provisions of Drugs & Cosmetics Rules, 1945. Drug Licensing Authority of Assam has issued notice to the companies not complying with the provisions of GMP.

(e): Regulatory and quality control provisions for Ayurvedic, Siddha, Unani and Homoeopathic drugs are prescribed in the Drugs & Cosmetics Act 1940 and the Rules 1945. The Central Government is vested with the powers to frame and amend the legal provisions provisions and their enforcement is done by the State Governments. The AYUSH medicines are not covered under the Price Control order of the Central Government. Following steps have been taken for quality control of AYUSH medicines-

i. Pharmacopoeia Commission of Indian Medicine & Homoeopathy and Pharmacopoiea Committees have been set up to lay down the quality standards of Ayurvedic, Siddha, Unani and Homoeopathic drugs, which are published in the respective pharmacopoeias and are mandatory for the manufacturers to follow in the manufacturing of these medicines.

ii. Good Manufacturing Practices (GMP) and requirements for issue of license to manufacture various types of Ayurvedic, Siddha and Unani medicines on the basis of evidence of safety and effectiveness are prescribed in the Drugs & Cosmetics Rules, 1945.

iii. Rules for indicating shelf-life or expiry date on the labels of the ASU&H medicines have been notified.

iv. Quality Certification systems have been introduced.

v. Essential Drug Lists and Guidelines of Good Clinical Practices published.

vi. Grant-in- aid is provided through the Centrally Sponsored Scheme of National AYUSH Mission for the quality control activities of ASU&H medicines including strengthening of state pharmacies, drug testing laboratories and enforcement framework.