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

LOK SABHA
UNSTARRED QUESTION NO. 3313
TO BE ANSWERED ON 12TH JULY, 2019

QUALITY CONTROL PROCESS FOR AYURVEDIC PRODUCTS

3313. SHRI N.K. PREMACHANDRAN:

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

(a) whether the Government is aware that lack of documented validation and quality control procedures for Ayurvedic product are adversely affecting the development of this sector;

(b) if so, the details thereof;

(c) the action taken by the Government for completing documented process validation and regulating batch to batch variation in product; and

(d) whether the quality assurance protocol is properly designed and if so, the details thereof and the action taken to improve the design?

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

(a) & (b): No, exclusive regulatory and quality control provisions for Ayurvedic medicines are in place under the Drugs and Cosmetics Act, 1940 and Rules there under and the reference standards of ingredients and Standard Operating Procedures of manufacturing are given in the Ayurvedic Pharmacopoiea, Formulary and other authoritative books. The legal provisions for Ayurvedic medicines are framed and amended on the recommendation of Ayurvedic, Siddha and Unani Drugs Technical Advisory Board, which is a statutory body under the provisions of Drugs & Cosmetics Act, 1940 to advise the Central and State Governments in technical matters of Ayurvedic, Siddha and Unani drugs. As per the existing provisions, compliance to quality standards of drugs prescribed in Ayurvedic Pharmacopoiea and Good Manufacturing Practices (GMP) is mandatory for the manufacturing of Ayurvedic products. Requirement of providing proof of safety and effectiveness of various categories of Ayurvedic medicines is prescribed in Rule 158-B of the Drugs & Cosmetics Rules, 1945. Ayurvedic drug manufacturing companies are also taking up WHO-GMP certification and AYUSH Premium Mark certification for promoting export market of their products, which is accounted for approximately USD 3.4 billion and estimated to grow at a compound annual growth

rate of about 16.2%. As of now no adverse impact of existing provisions is reported against the development of Ayurveda sector.

(c) & (d): State Governments are responsible to enforce the legal provisions for Ayurvedic drugs for which Licensing Authorities, Drug Inspectors and Government Analysts are appointed to ensure adherence to the prescribed standards and protocols of manufacturing and quality control of products. Central Government is empowered to issue need based regulatory advisories and directions to the State Governments for effective enforcement of quality control provisions.

…….