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

LOK SABHA
STARRED QUESTION NO.42
TO BE ANSWERED ON THE 26TH FEBRUARY, 2016
QUALITY AND SAFETY OF AYUSH MEDICINES

***42. SHRIMATI VANAROJA R.:**

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

(a) whether the Government has received recommendations/suggestions to take steps for ensuring quality of AYUSH medicines including changes in the relevant rules/laws;

(b) if so, the details thereof and the response of the Government thereto indicating the reasons for delay in formulating necessary rules/laws; and

(c) the corrective steps being taken in this regard along with the time by which necessary changes are likely to be made?

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

(a) to (c): A statement is laid on the Table of the House

STATEMENT REFERRED TO IN REPLY TO LOK SABHA
STARRED QUESTION NO 42 FOR 26TH FEBRUARY, 2016

a) to (c) Yes Madam, Department-related Parliamentary Standing Committee on Demand for Grants made recommendations in its reports for strengthening of laboratories and enforcement mechanism at Central and State level, control of misleading advertisements, revision of the quality control scheme and establishment of separate Central Drugs Controller of AYUSH to ensure quality control of AYUSH medicines. Ministry of AYUSH has also received the recommendations of the AYUSH Task Force set up by the Government under Chairmanship of Prof. H.R. Nagendra. Following actions have been taken in pursuance of these recommendations observing the stipulated procedures:-

i. Quality Control Scheme of ASU&H drugs has been approved by merging the same in National AYUSH Mission with enhanced funding pattern and addition of more components. Financial support is being provided to the States through National AYUSH Mission for strengthening of infrastructural and functional capacities of the laboratories and pharmacies, engagement of technical manpower, strengthening of the enforcement mechanism, testing of drugs and documentation and dissemination of quality control materials related to ASU&H drugs. Twenty Nine (29) states have availed financial support for this purpose during 2015-16 and forty one laboratories for testing of Ayurvedic, Siddha and Unani drugs are approved under the provisions of the Drugs and Cosmetics Rules, 1945.

ii. Amendment of Drugs & Cosmetics Rules notified in May 2015 for prohibiting the use of prefix and suffix with the names of Ayurvedic, Siddha and Unani drugs as defined under section 3(a) of the Drugs & Cosmetics Act, 1940.

iii. Draft Rules for the shelf life or expiry date of the ASU medicines notified on 24th November, 2015 for inviting comments and suggestions of the stakeholders. Comments and suggestions of the stakeholders have been received and are being examined for finalizing the proposed rules.

iv. In order to prohibit the menace of misleading advertisements and exaggerated claims of ASU drugs, draft rules have been framed and sent to Law Ministry for vetting. Ministry of Health & Family Welfare has informed that one of the proposals under consideration is that provisions of the Drugs and Magic Remedies Act can also be integrated into the new Act for the Drugs, Medical Devices and Cosmetics.

v. Regulatory provisions for the education and profession of pharmacy of Ayurveda, Siddha, Unani, Sowa-rigpa and Homeopathy have been drafted in the form of 'The Indian Medicine and Homoeopathy Pharmacy Central Council Bill, 2016'. The Bill has been circulated for inter-ministerial appraisal and consultation with the States.

vi. Ministry of AYUSH has made specific recommendations to the Department of Health and Family Welfare for making enabling provisions *inter-alia* for inclusion of Sowa-Rigpa and Homoeopathy drugs in the ambit of Chapter IV-A of the Drugs & Cosmetics Acts, 1940, which is intended for amendment for various regulatory provisions. Ministry of Health & Family Welfare has informed that the proposed amendment Bill has been considered by a Group of Ministers and the likely proposal now is to draw a completely new Bill.

vii. Setting up of a structured Central Regulatory Framework for AYUSH drugs is in process and twelve posts of Deputy / Assistant Drug Controllers and Inspectors of ASU&H have been notified on 17th February, 2016.

viii. Report with recommendations of the AYUSH Task Force *inter-alia* for quality control and certification of AYUSH medicines is being examined in the Ministry of AYUSH.

Steps taken above in pursuing the recommendations required detailed consultative process involving stakeholders and concerned departments to finalize the intended outcomes. The timelines for making or amending the legal provisions in accordance with the given recommendations cannot be fixed since the procedural steps required for amendment of Rules and framing of legislation have to be followed.