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

RAJYA SABHA UNSTARRED QUESTION NO.166 TO BE ANSWERED ON 20th July, 2021

LICENSE FOR PATANJALI AYURVED'S CORONIL

166 DR. L. HANUMANTHAIAH:

Will the Minister of AYUSH be pleased to state:

- (a) whether Government has upgraded the license for Patanjali Ayurved's Coronil from an "immunity booster" to a "supporting measure" in treating COVID-19;
- (b) if so, the details of the data/studies based on which such an upgrade was approved and the limitations of such data/studies, if any;
- (c) the details of the decision-making process in granting such approval;
- (d) the laws/rules/policies/guidelines under which such approval was granted; and
- (e) the definitions of "immunity booster" and "supporting measure" under the applicable laws/rules/policies/guidelines, and the procedure and conditions subject to which such license is granted?

ANSWER

THE MINISTER OF STATE OF THE MINISTRY OF AYURVEDA, YOGA & NATUROPATHY, UNANI, SIDDHA AND HOMOEOPATHY (SHRI MAHENDRABHAI MUNJAPARA)

- (a) to (c): The Application titled, "updating the AYUSH license for Divya Coronil tablet from "Immunity booster" to "Medicine for COVID-19" submitted by Patanjali Research Foundation Trust, Haridwar, Uttarakhand to this Ministry, was placed before the Interdisciplinary Technical Review Committee (ITRC) setup by Ministry of AYUSH on 28.10.2020 for examination of the applications/claims on patent & propriety (P&P) ASU&H medicines with new indications or repurposing of licensed P&P, ASU&H medicines for COVID-19. It was suggested that it may be used as supporting measure in COVID. The State Licensing Authority was also informed that *Coronil* tablet may be used as supporting measure in the management of COVID-19 without claiming cure.
- (d) & (e): The regulatory provisions for granting license and approval of Ayurvedic, Siddha, Unani and Homoeopathy drugs are prescribed under Drugs and Cosmetics Act,1940 and Rules 1945. Section 3(a) and Section 3(h) defines all Ayurvedic, Siddha, Unani medicines intended for internal or external use for or in the diagnosis, treatment, mitigation or prevention of diseases or disorder in human beings or animals, and manufactured exclusively in accordance with the formulae described in, the authoritative books of Ayurvedic, Siddha and Unani Tibb systems of medicine, specified in the First Schedule.

The State Licensing Authority Uttarakhand has granted license of drug "Coronil" after examination of the application submitted by the applicant. The State Licensing Authority Ayurveda government of Uttarakhand was informed that "Coronil" Tablet may be used as supporting measure in the management of COVID-19 without claming cure.