F. No. t. 11020/1/2020-DCC (AYUSH)

Government of India

Ministry of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy (AYUSH)

Dated: 28th July, 2020.

ORDER

Whereas in the wake of COVID-19 outbreak, Ministry of AYUSH vide Gazette Notification No. L.11011/8/2020/AS dated 21st April, 2020 issued guidelines of the requirements to enable the conduct of research studies/clinical trials on Ayurveda, Siddha, Unani and Homoeopathy (ASU&H) interventions on COVID19;

Whereas, as per Rule 158-B of the Drugs and Cosmetics Rules, 1945, proof of effectiveness for new indication or use is inter alia required for granting license/approval to manufacture for sale of Ayurvedic, Siddha and Unani medicines;

Whereas it has come to the notice of Central Government in the Ministry of AYUSH that approvals are being given for the medicinal products selected/registered for the clinical trials/research studies and spurious claims and misleading advertisements made in the media about the treatment of COVID-19 patients;

Therefore in order to make the process of product approval/licensing consistent at State/UT level for the purpose of effective quality control of Ayurvedic, Siddha, Unani and Homoeopathic medicines underwent clinical trials/research studies for COVID-19 and in exercise of the powers of Central Government, conferred under Section 33P of the Drugs and Cosmetics Act, 1940, it is hereby directed to all State/UT Licensing Authorities to forward license application of such formulations with details and results of the clinical trial/research study for verification by the Central Government in the Ministry of AYUSH. State/UT Licensing Authority shall grant the approval or license to manufacture for sale of any such formulation only after obtaining clearance from the Central Government.

Adviser (Ay.) and Head, ASU&H Drugs Policy Section

To

i) Principal Secretaries/Secretaries (Health/AYUSH) of all States/UTs.

ii) State Licensing Authorities/Drug Controllers of AYUSH