Subject: Expediting the process for grant of approval/license/renewal of license for manufacturing of ASU immunity boosting healthcare products and sanitizers- reg.

Regulatory and quality control provisions for the manufacturing of Ayurvedic, Siddha and Unani drugs/medicines under Drugs and Cosmetics Act, 1940 and Rules thereunder are enforced by the Licensing Authorities/Drug Controllers appointed by the State/UT Government. Due to COVID 19 outbreak, the need for public use of ASU based immunity boosting products for healthy people and hand sanitizers has been significantly emphasized and their demand has increased manifold. In this regard, some drug manufacturers engaged in or interested to proceed for producing ASU ingredients-based such products have represented to the Central Government about the problems being faced in the States/UTs for grant or renewal of license/approval in the current situation.

Whereas Hon’ble Prime Minister during interaction with the AYUSH stakeholders via video-conference on 28th March, 2020 inter alia suggested for ASU medicines manufacturers to utilize their resources towards producing essential items like sanitizers and highlighted the impact of traditional practices towards boosting immunity of healthy people to play the important role in India’s fight against COVID-19.

Accordingly, in view of the urgent need of meeting the challenge of increased demand of aforesaid ASU healthcare products, all the State AYUSH Licensing Authorities/Drug Controllers and Expert Committees thereunder are hereby directed to complete the licensing/approval/renewal process expeditiously and dispose of the applications of the manufacturers maximum within a week’s time provided the prescribed standards and relevant provisions of the Drugs & Cosmetics Rules, 1945, in terms of use of ingredients and permitted excipients in accordance with the authoritative books including Pharmacopoeias and Formularies, are fulfilled. It is also appealed to send the list of manufacturers and details of such ASU products being licensed/approved under your jurisdiction.

This is issued with the approval of Secretary (AYUSH), Government of India.

Adviser (Ay.) and Head, Drugs Policy Section

To

All State/UT Licensing Authorities and Drug Controllers of AYUSH

Copy for information to:
   i) Principal Secretaries/Secretaries (Health/AYUSH) of all States/UTs.
   ii) ASU Drugs Manufacturers Associations