Memorandum

The second wave of COVID–19 has imposed immense pressure on the healthcare infrastructure due to increased need for hospitalization. Therefore, there is a need for treatment of asymptomatic subjects and subjects with mild to moderate Covid-19 symptoms either through home isolation or through COVID care centers (including those of AYUSH). Ministry of AYUSH is issuing guidelines and protocols for public as well as practitioners from time to time. 

Asvagandha and Guduchi like remedies are already introduced in the prophylactic care. The recent scientific studies conducted by AYUSH-CSIR research team, provided evidence that usage of the AYUSH-64 formulation has shown early recovery, shortened duration of hospital stay, and prevention of serious complications when administered along with standard of care. The encouraging outcomes of AYUSH-CSIR collaborative multi-centric studies at reputed medical institutions also shown to help reduce symptoms, disease progression to severe form and duration to become COVID Negative in the management of asymptomatic, mild & moderate cases of Covid 19.

2. AYUSH 64 is also recommended in “National Clinical Management Protocol based on Ayurveda and Yoga” vetted by Joint Task Force for Covid Management, released last year which was vetted by National Task Force on Covid management.

3. Therefore, Ministry of AYUSH has decided to provide widespread distribution of AYUSH-64 along with the standard of care. The AYUSH-64 formulation which is developed by CCRAS is already available with about 30 manufacturers. Few more manufacturers are obtaining permission to commercialize. In this connection Ministry of AYUSH will appreciate the manufacturers if they provide the information about the availability of their medicines at various outlets. These details will be posted on the AYUSH dash board to enable the Ayush physicians
and others to know about the region-wide availability. Since, AYUSH-64 is recommended along with standard of care, Ayush physician consultation is required.

4. IMPCL, A PSU under Ministry of Ayush is so far able to supply AYUSH-64. However, if there is increased demand, the State Governments / UT may be allowed to purchase the AYUSH-64 at the price being offered by IMPCL i.e., Rs. 104.80 per 40 tablets pack + Tax without going for any tender under National Ayush Mission. National Institutes / Research Councils under Ministry of Ayush which is engaged in large scale distributions also may be allowed to procure in similar manner. However, the commercial promotion is sole responsibility of the individual manufacturer and Ministry of AYUSH has no role to play. Their information will be displayed on the AYUSH web site and they will be connected with NMPB for any raw material related guidance.

5. Ministry has issued orders dated 27.4.2021 and 29.4.2021 (copy attached) to all the State AYUSH Licensing Authorities/Drug Controllers and Expert Committees there under to allow the licensed manufacturers for AYUSH-64 under their jurisdiction to include new indication of AYUSH 64 for repurposing as an intervention for the management of asymptomatic, mild to moderate COVID-19 in addition to existing indication(s) and to expedite the process of the licensing/approval of such applications for the manufacturing of AYUSH 64 medicine, provided the prescribed standards and relevant provisions of the Drugs & Cosmetics Rules, 1945, are fulfilled.

6. Hon’ble Minister of State, Ministry of Youth Affairs and Sports and Ministry of AYUSH (Independent Charge) Shri Kiren Rijiju on 7th May 2021 through a virtual conference has launched a Nationwide distribution campaign of AYUSH 64 and Kabasura Kudineer for the benefit of the vast majority of out of hospital Covid-19 patients. The Ministry is also engaging with States / UT, NGOs and volunteers for nationwide distribution of AYUSH-64 and Kabasura Kudineer.

7. It may also be recalled that a meeting was held on 30.4.2021 with Manufacturers whom the technology of AYUSH 64 has been provided by CCRAS through NRDC. In the said
meeting, a stock of the manufacturer’s capabilities, timelines and constraint including raw material issues which are required for bulk and fast track manufacturing of AYUSH 64 formulations were deliberated so that the same can be sorted out with collaborative efforts.

8. Ministry of Ayush reiterates its commitment to remove the bottlenecks, if any for the production and distribution of AYUSH-64 and Kabasura Kudineer by Ayush Industries for the management and mitigation of Covid 19. This issues with the approval of Secretary (AYUSH).

Yours sincerely

Digitally signed by CHINTA SRINIVAS RAO
Date:Sun May 09 17:46:34 IST 2021

(Dr S.R. Chinta)
Deputy Adviser

Enclosed: As above

To,

(i) All manufacturers to which AYUSH 64 Technology has been transferred through CCRAS;

Copy to:

(i) Director General, Central Council for Research in Ayurvedic Sciences (CCRAS), Janakpuri, New Delhi;

(ii) All State/UT Ayush Directorates.

(iii) All Manufacturer’s Associations of Ayush Medicines.
MEMORANDUM

Due to the COVID 19 outbreak, the need for public use of ASU based immunity boosting products and medicines has been significantly emphasized and their demand has increased manifold. AYUSH 64, an Ayurvedic medicine was developed in compliance to all regulatory requirements and quality and pharmacopoeial standards by the Central Council for Research in Ayurvedic Sciences (CCRAS), an apex body for research in Ayurveda under the Ministry of AYUSH. Based on its ingredients having notable antiviral, immune-modulator and antipyretic properties and as recommended by the Interdisciplinary Committee for Inclusion of Ayurveda and Yoga in the management of mild COVID-19, the AYUSH 64 already was included in the National Clinical Management Protocol Based on Ayurveda and Yoga Interventions for the management of Asymptomatic and mild to moderate cases of COVID-19. (Copy enclosed).

2. It was further subjected to multi centric clinical trial for studying its efficacy in COVID 19 patients under joint initiative of CSIR-Ministry of AYUSH. The trial was completed and it was found that Add-on arm had showed a significant reduction in time to recovery (primary efficacy) as compared to the standard of care arm. Also, the safety and tolerability profile was good.

3. As regards the quality of life, Significant improvement in physical health in the Add-On Arm on hospital discharge and Borderline statistical improvement (p<0.07) has been observed in psychological health on study completion.

4. The Monitoring Committee of CSIR-Min. of AYUSH Joint Initiative on Clinical Trials of four AYUSH Interventions for COVID-19 has also recommended that AYUSH-64 be positioned as an intervention for the management of asymptomatic, mild to moderate COVID-19 through repurposing.

5. In this regard, since the regulatory and quality control provisions for the manufacturing of Ayurvedic, Siddha and Unani drugs/medicines under Drugs and Cosmetics Act, 1940 and Rules there under are enforced by the Licensing Authorities/Drug Controllers appointed by the State/UT Government, all the State AYUSH Licensing Authorities/Drug Controllers and Expert Committees there under are hereby informed to allow the licensed manufacturers for AYUSH-64 under their jurisdiction to include new indication of AYUSH 64 for repurposing as an intervention for the management of asymptomatic, mild to moderate COVID-19 in addition to existing indication(s).
6. The companies who are interested in technology transfer of AYUSH-64 may contact CCRAS (dg-ccras@nic.in, iprecras@gmail.com) /National Research Development Corporation (vkjain@nrdc.in). Technical support to the ASU drugs manufacturers regarding manufacturing of AYUSH-64 will be provided by Central Council for Research in Ayurvedic Sciences (CCRAS) as per the need. State Licensing Authorities are requested to expedite the process of the licensing/approval of such applications for the manufacturing of AYUSH 64 medicine, provided the prescribed standards and relevant provisions of the Drugs & Cosmetics Rules, 1945, are fulfilled.

This issues with the approval of Secretary, Ministry of Ayush.

To,

All State/UT Licensing Authorities and Drug Controllers of AYUSH

Copy for information to:

i. Director (AYUSH) of all States/UTs.

ii. ASU Drugs Manufacturers Associations

iii. DG, CCRAS
Please refer to this Ministry memorandum no T.18020/1/2020-DCC-Part(1) dated 27.04.2021, which has been sent to all Licensing Authorities and Drug Controllers of AYUSH to expedite the process of licensing/approval of such applications for the manufacturing of AYUSH 64 medicine, provided the prescribed standards and relevant provisions of the Drugs & Cosmetics Rules, 1945 are fulfilled.

In this connection, copy of the quality parameter of AYUSH 64 containing quality standard of ingredients is being sent for guidance and further necessary action.

Encl- As above

To,

All State/UT Licensing Authorities and Drug Controllers of AYUSH