GOVERNMENT OF MEGHALAYA HEALTH & FAMILY WELFARE DEPARTMENT

No. Health.277/2020/Pt/51

Dated Shillong, the 15th June, 2021.

From:

Shri. T. G. Momin, MCS,

Joint Secretary to the Government of Meghalaya,

Health & Family Welfare Department.

To:

The Director of Health Services (MI),

Meghalaya, Shillong.

Subject:

Advisory regarding oxygen concentrators.

Sir,

I am directed to forward herewith the 'Advisory Regarding Oxygen Concentrators Suitable for COVID-19 Case Management in Home Settings' issued by the Central Drugs Standard Control Organization, Government of India, for favour of your information and necessary action.

Yours faithfully,

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Joint Secretary to the Government of Meghalaya, Health & Family Welfare Department

Memo No. Health.277/2020/Pt/51-A

Dated Shillong, the 15th June, 2021.

Copy to:

- 1. The Principal Secretary to the Government of Meghalaya, Health & Family Welfare Department.
- 2. The Commissioner & Secretary to the Government of Meghalaya, Health & Family Welfare Department/ Urban Affairs Department.
- 3. The Mission Director, National Health Mission, Meghalaya.
- 4. The Director, Information and Public Relations for publicity through the official website.
- 5. The State Informatics Officer, NIC, Meghalaya, for publicity through the Health & Family Welfare Department/COVID-19 websites.

By order, etc.,

Joint Secretary to the Government of Meghalaya, Health & Family Welfare Department No. X 11035/283/2020- DR

Government of India Ministry of Health & Family Welfare (Drug Regulation Section)

Dated: May 17, 2021

Nirman Bhawan, New Delhi - 110011

Office Memorandum

Sub.: Implementation of advisory regarding oxygen concentrators suitable for Covid 19 cases. – reg.

I am directed to refer to the Advisory regarding "oxygen concentrators suitable for Covid -19 management for home settings" issued by the Drug Controller General (India), Central Drugs Standard Control Organization, Ministry of Health & Family Welfare, vide F.No.18-04/2021-DC dated 16.05.2021 (Copy enclosed). The advisory has already been sent by DCGI to all the State Drug Controllers.

2. It is requested that the advisory may kindly be adequately publicized for the information and guidance of, both the sellers/retailers and the public, and also got duly implemented.

(Bikash R Mahato)

Under Secretary to the Government of India

Encl: As above

To

Additional Chief Secretaries/Principal Secretaries/Secretaries, Department of Health & Family Welfare, all States/UTs.

Copy to : (i) PPS to Secretary (HFW), Additional Secretary (VS), Director (Drugs)

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Its - 44410/21.

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F.No. 18-04/2021-DC Central Drugs Standard Control Organization Government of India Ministry of Health and Family welfare

FDA Bhawan, New Delhi Dated the 16th May, 2021

ADVISORY NOTICE

Advisory regarding Oxygen Concentrators suitable for COVID-19 case management in Home settings

- Oxygen concentrator is an electrically powered medical device designed to concentrate oxygen from ambient air. These devices deliver oxygen at the bedside, typically through an attached nasal cannula (or prongs), to a patient requiring oxygen therapy. The intended use or clinical purpose of oxygen concentrators is the delivery of low-flow, continuous, clean and concentrated oxygen, preferably with concentration of 90% or more, from room air (which usually contains only 21% oxygen).
- At present various models of oxygen concentrators, having different capacities of continuous flow(1 to 10 Liters/Min) and widely varying concentration of oxygen, are being marketed.
- The Ministry has from time to time advised that oxygen concentrators with flow capacity of 5 litre per minute or more and delivering oxygen with concentration of 90% or more are suitable for management of COVID-19 patients at the COVID Care Centers, the Dedicated COVID Health Centers and in home settings. The World Health Organisation has also precribed these norms for oxygen concentrators.
- Many peopleare not aware about these minimum parameters of Oxygen
 Concentrators and therefore may be using the concentrators that are not suitable for
 COVID-19 case management. This advisory is issued to informpeople about
 minimum standards of Oxygen Concentrators for COVID-19 case management, for
 use especially in home settings.
- It is advised that Oxygen Concentrators having following specifications may be used in home setting:
 - Provides a continuous flow of concentrated oxygen (> 90%) from room air through one oxygen outlet.

- Minimum Continuous flow of up to 5 L/min or more.
- Contains oxygen monitor to verify concentration.
- Digital or analogue meter that displays cumulative hours of device operation.
- It is advised that Oxygen Concentrators of less than 5 litres per minute capacity may not be sold under the misleading label of "for home based COVID care."
- · It is further advised that Oxygen Concentrators must be purchased with:
 - Consumables required to operate.
 - User care instructions and protocols, including guidance for replacement of accessories and consumables and safe decontamination of reusable parts, indicating if they are generic or brand related.
 - Technical maintenance protocols.
- It is strongly advised that all sellers must prominently display the following information, for each model of Oxygen Concentrator for sale -
 - Continuous flow capacity in litre per minute.
 - Percentage of Oxygen that a concentrator generates; and
 - The Maximum Retail Price.

The aim of this advisory is to provide minimum parameters, that must be verified by people before using a Oxygen Concentrator for COVID-19 case management in Home settings.

(Dr. V.G. Somani)

Drugs Controller General (1)

To All State UT Drugs Controllers