17 March 2022

Dr Tedros Adhanom Ghebreyesus
Director-General
World Health Organization (WHO)
Geneva, Switzerland

Open Letter: Proposed Medical Oxygen Revisions to the International Pharmacopoeia and the Global Access to Oxygen Agenda

Dear Dr Tedros,

We are writing on behalf of several members and other organizations, including the World Federation of Societies of Anesthesiologists (WFSA), the ISO Technical Committee 121 (Anaesthetic and Respiratory Equipment), and the International Association of Manufacturers of Medical Gas Generators for Hospitals (MEDIGHAM), who have expressed concerns that the current draft revision (**October 2021**) to the International Pharmacopoeia could further restrict access to medical oxygen by making it difficult for hospitals to work with oxygen sourced from both oxygen 93% and oxygen 99.5%.

To ensure that the International Pharmacopoeia does not unwittingly become an instrument used to further restrict access to oxygen, or to effectively lock hospitals into using oxygen from only one source, we have proposed clarifications that make it clear that oxygen from both sources can be safely mixed and provided to patients (see below).

This is particularly relevant for hospitals and patients across low- and middle-income countries where oxygen infrastructure is rapidly being installed and refurbished to treat COVID-19 patients. Many health facilities are introducing oxygen for the first time or being required to re-examine which mix of solutions will be most cost-effective for them.

We do not want to see hospitals unable to choose or change to the most effective solution(s) based on their local situation.

We welcome a discussion with WHO and the members of the **WHO Expert Committee on Specifications for Pharmaceutical Preparations** before the current draft revision is presented to their 56th meeting from 25 April to 2 May 2022.

We applaud your team for revising the International Pharmacopoeia at a time when the demand for medical oxygen has surged and many hospitals have faced shortages and preventable deaths. We look forward to working with WHO and the Expert Committee to ensure that this revision contributes effectively to the access to oxygen agenda.

Sincerely

SIGNED

Leith Greenslade
Coordinator
Every Breath Counts Coalition

Every Breath Counts Proposed additional language to the Revision of Medicinal Oxygen in The International Pharmacopoeia in orange below

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[Note from the Secretariat. With the revision of the monograph on Oxygen, it is intended:

- to clarify that WHO Member States, considering options for increasing the supply of medicinal oxygen to treat COVID-19 and other patients, can safely apply oxygen generated by:
    - Oxygen Generation Plants, which use Pressure Swing Adsorption (PSA) or Vacuum Swing Adsorption (VSA) technologies to generate 90 to 96% pure oxygen, referred to in the draft revision as “Oxygen 93%”;
    - Air Separation Units, which use cryogenic technology to generate 99.5% pure oxygen, referred to in the draft revision as “Oxygen 99.5%”, and/or
    - **Medical oxygen generated from oxygen 93% and oxygen 99.5% sources in the defined quality can be safely mixed and administered to patients at the health facility level; and**
- to define quality requirements for these two products.

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Definition. Medicinal oxygen is Oxygen 93% or Oxygen 99.5%. It is applied in combination with ambient or compressed air of a suitable quality or in pure form, depending on the clinical medical necessity. **Medical oxygen generated from oxygen 93% and oxygen 99.5% sources in the defined quality can be safely mixed and administered to patients at the health facility level.**

Cc.
World Health Organization (WHO)
Dr Mariângela Batista Galvão Simão, Assistant Director-General, Access to Medicines and Health Products
Dr Clive Ondari, Director, Health Products Policy and Standards, Norms and Standards for Pharmaceuticals
Dr Sabine Kopp, Team Lead, Medicines Quality Assurance and the International Pharmacopoeia
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Select members of the WHO Expert Committee on Specifications for Pharmaceutical Preparations
Dr Petra Dörr, Bern, Switzerland
Dr Adrian Krauss, Canberra, Australia
Professor Eliangiringa Amos Kaale, Dar es Salaam, United Republic of Tanzania
Dr Luisa Stoppa, Rome, Italy
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