

## access to medicine FOUNDATION

#### MEETING REPORT

# The Global Oxygen Alliance Community of Practice: Roundtable 3

November 13, 2025

#### FROM TALK TO ACTION: WHY THIS ROUNDTABLE MATTERS

This roundtable marked the third time that the <u>Global Oxygen Alliance</u> (GO<sub>2</sub>AL) Community of Practice (CoP) brought together a multistakeholder network dedicated to expanding oxygen access in low- and middle-income countries (LMICs) and was facilitated by the <u>Access to Medicine Foundation</u> on behalf of GO<sub>2</sub>AL. This network covers multiple segments of the oxygen ecosystem, from producers to distributors to oxygen delivery to the patient. The CoP aims to strengthen collaboration across these actors and to develop industry-based scale-up models that demonstrate public-private partnerships for sustainable, equitable and reliable access to medical oxygen in LMICs. The session focused on launching separate CoPs for three different pilot countries, reviewing regulatory challenges and exploring collaboration opportunities and potential outcomes.

COVID-19 highlighted the urgent need for oxygen access and demonstrated what rapid, collaborative action can achieve. Post-pandemic, there is an opportunity to assess investments made and draw lessons to inform future sustainable investments. However, since COVID-19, investments in oxygen systems have sharply declined among donors and multilateral partners, putting at risk the significant progress achieved during the pandemic. To ensure long-term sustainability, the oxygen sector will require stronger and more effective public-private partnerships. With GO<sub>2</sub>AL's current strategic cycle running until 2030, there is an urgent need to demonstrate tangible results quickly and enable countries to own and sustain oxygen systems beyond external funding. To support this, effective collaboration must be characterised by clear two-way information sharing, transparency about challenges and joint problem-solving.





Senegal

CoP

South

Africa CoP

Uganda

COP

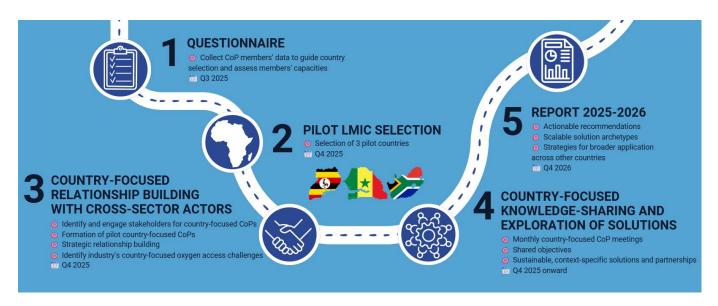
GO<sub>2</sub>AL

Community of

#### **KEY INSIGHTS & TAKEAWAYS**

#### GO<sub>2</sub>AL CoP Industry Action Plan 2025-2026

The March and May 2025 GO<sub>2</sub>AL CoP roundtables highlighted the need to balance global alignment with a bottom-up approach, identifying country-specific industry challenges and oxygen gaps, and strengthening coordination among stakeholders to support sustainable country-led solutions. In response, an Industry Action Plan was developed to identify oxygen challenges in three strategically selected pilot countries and outline actionable steps to address them. Lessons from this work will inform adaptable frameworks to support wider expansion of oxygen access across other LMICs.



#### Targeting impact: pilot country selection

South Africa, Senegal and Uganda were selected based on CoP members' country preferences, disease burden (e.g. COVID-19 excess mortality rate) and the status of national oxygen roadmaps. Practical considerations

included feasibility of implementation, the in-country presence of  $GO_2AL$  organisations, existing relationships with ministries of health and regulatory agencies, and where our collective presence and partnerships would

position us for success.

The GO<sub>2</sub>AL CoP is an overarching network, with roundtables serving as cross-country update meetings to share progress, learn from one another and hear from guest speakers. Within this CoP, three country-specific CoPs operate, each with its own members, monthly meetings and specific objectives.

Collectively, these country CoPs bring together a growing network of oxygen companies and organisations, with 12 in Senegal, 19 in South Africa and 26 in Uganda. Each CoP includes international and local representatives across the oxygen ecosystem and engages with in-country GO<sub>2</sub>AL representatives, ministries of health and regulatory agencies. The main work takes place within these three CoPs, which serve not only to develop strategies for increasing oxygen access at country level but also to capture and track industry action and progress in LMICs.





#### The power of holistic approaches for country-level oxygen access

The East Africa Program on Oxygen Access, launched in 2024, provides a concrete example of a sustainable public-private partnership that did not emerge overnight but was built on a thorough understanding of the local ecosystem and market. This partnership aligns public-sector commitments with industry incentives, enabling companies to maintain viable business models while reducing prices to sustainably affordable levels for (sub)national governments and patients. The program was grounded in a comprehensive ecosystem analysis, assessing existing production, functional equipment, service and maintenance arrangements, market gaps and financing, to target investments effectively. The program demonstrates that successful initiatives require a holistic approach, integrating multiple industry players, production modalities and both public and private market considerations, all aligned with national plans for oxygen access. As the pilot CoPs are in their early stages, this example highlights the importance of iterative, collaborative development, where solutions are tested, refined and scaled collectively.

#### Uganda case study: Breaking down barriers to local oxygen markets - Oxygen CoLab

Barriers to a sustainable local oxygen market in Uganda				Potential pathways forward
200	Fragmented market demand	Fragmented demand and ad hoc contracts → unpredictable revenue → many private companies and SMEs struggle to access capital and grow		<ul><li>Organise reliable demand</li><li>Aggregated facility demand and purchasing</li></ul>
	Regulatory barriers to market entry	<ul> <li>Unclear and expensive regulatory pathways: onerous requirements and lengthy timelines for registration and certification</li> <li>Limited capacity within regulatory agencies for QA, compliance enforcement and post-market surveillance</li> </ul>		<ul> <li>Implementation of risk-based tiering of market actors with proportionate requirements</li> <li>Define clear regulatory milestones and timeline phases</li> <li>Document and publish clear requirements of licensing and certification</li> <li>Work with regulators to co-develop a framework that will support market entry</li> <li>Provide targeted capacity building for regulators</li> </ul>
**************************************	Rigid procurement policies	Centralised procurement systems limit flexible contracting or rapid purchase during emergencies.		Develop and adopt policies and procurement frameworks enabling flexible contracting and decentralised ordering and delivery.
	Lack of transparent budgeting	<ul> <li>Oxygen spending is hidden within general health budgets, which limits proper forecasting and planning for investment.</li> <li>Centralised revenue pooling prevents reinvestment</li> <li>Insufficient data to justify new investment</li> </ul>		<ul> <li>Generate data to create specific budget lines for oxygen</li> <li>Advocate for sustainable financing</li> <li>Developing investment cases and aligning donor and government resources</li> </ul>





#### Technical and market realities: what participants highlighted

- Oxygen purity: <u>ISO Technical Committee 121</u> is proposing two recognised categories: 'Oxygen 90+' and 'Oxygen 99+'. Current WHO pharmacopeia definitions may restrict uptake of concentrators delivering 90-99%. Regulatory bodies and national pharmacopeias should be advised to recognize these two oxygen types, the variability in their production technologies and the range of medical devices that deliver them.
- Regulatory landscapes: Many sub-Saharan African countries are affected by monopsony and regulatory capture, favouring large, well-resourced players. Strict quality and safety regulations, while important, create high barriers to entry for smaller, healthcare-focused oxygen suppliers. These barriers limit market maturation and the development of strong local oxygen delivery markets. Any review of regulatory requirements should consider the trade-off between maintaining high quality standards and enabling the growth of local markets.
- Import duties and logistics: Concerns about high import taxes (sometimes reported at 45-60%) on oxygen equipment, long customs clearance timelines and shipping delays that can exceed 9-12 months.
- Maintenance and sustainability: Need to plan for ongoing maintenance, spare parts, and capacity building for biomedical equipment to ensure investments remain functional and avoid equipment breakdowns.
- **Power and maintenance challenges**: Inconsistent power quality across countries affects PSA oxygen equipment, increasing maintenance costs, and underscores the need to address both infrastructure and ongoing service requirements

### Tackling regulatory roadblocks to oxygen access in South Africa – South African Health Products Regulatory Authority (SAHPRA)

Regulatory Authority (SARPRA)						
Opportunities for alignment						
<b>%</b>	Clarifying classifications and regulatory requirements	Aligning on the product classification (medical oxygen as medicine vs. PSA equipment and cylinders as medical devices), will help clarify the appropriate regulatory pathway and ensure a smooth, coordinated approach.				
<b>⊕</b> ©	Enhancing understanding of regulatory stakeholders' mandates	Clarifying mandates and aligning priorities between companies and various institutions (SAHPRA, SABS, SAPC, NRCS, the Departments of Health; Trade, Industry and Competition) will support effective multi-stakeholder engagement and coordinated efforts.				

#### >>> Possible pathways forward

- Collaborate with relevant institutions (e.g. SABS) to develop clear product-specific guidelines and standards (potentially using AI) and update outdated standards
- Establish engagement channels such as workshops, (virtual) meetings and Q&A/FAQ publications on regulatory compliance and related regulatory inquiries to facilitate dialogue and strengthen alignment between regulators and companies on oxygen access objectives.
- Map the oxygen value chain and stakeholders, with the added benefit of revealing potential gaps.
- Engage, support and communicate the requirements to the relevant ministries (e.g. Health, Trade, Industry and Competition) to ensure coordinated action on oxygen access.





#### Additional proposed pilot CoP topics to unpack

- Continental regulatory harmonisation: By developing a broad, continent-wide regulatory guideline that can still be aligned with each country's legal framework. Although administrative differences will remain, the technical requirements should be harmonised as much as possible to promote regulatory convergence across all member states. This continent-wide harmonisation of medical oxygen definitions, standards and regulations could be advanced through engagement with the African Medicines Agency, offering our pilot countries as regions to test and refine this streamlining effort.
- Conducting a gap analysis would be useful to better understand the oxygen landscape in the different pilot countries, particularly to identify how significant the gaps are in lower-level healthcare facilities such as regional hospitals, health centre (HC) IVs, and HC IIIs.
- **Data prioritisation**: Discuss which data to prioritise, such as equipment functionality, oxygen consumption, or both, and ensure government ownership to support sustainable forecasting, supply planning and decision making.
- **Stricter regulatory oversight** is needed to prevent misuse of oxygen by non-medical industries and to protect patient safety.
- Advocacy alignment: Connect the CoP's work with the ongoing efforts to set up national advocacy coalitions for oxygen access, ensuring both initiatives run in parallel and share insights to strengthen overall impact.

#### Three pillars of support within the GO<sub>2</sub>AL CoP to accelerate oxygen access

- 1. Navigating regulatory challenges within the GO<sub>2</sub>AL CoP
  - The World Health Organization is finalising a <u>Regulatory Considerations for the Life Cycle of Medical Oxygen</u> guidance document. This document is primarily intended to provide recommendations for National Regulatory Authorities on the regulation of medical oxygen throughout its life cycle, mainly focusing on oxygen production, control and distribution. It also helps manufacturers, importers and distributors understand the requirements needed to ensure its quality, safety and effective delivery to patients.
  - GO<sub>2</sub>AL's Working Group 5 ('Strategic Information') is developing a concept note for a consolidated, industry-facing guidance package outlining regulatory expectations for medical oxygen products and systems in targeted geographies. The work aims to help industry actors more easily navigate classification requirements, approval pathways, responsible authorities and key compliance considerations.
- 2. Strategic connections: Facilitation and brokering of relationships with in-country ministries of health and regulatory bodies to navigate regulations, align with national priorities and support collaborative solutions.
- 3. Improved access to opportunities: Mechanisms to enhance stakeholder access to relevant opportunities are currently under discussion.

#### WHAT COMES NEXT: KEEPING MOMENTUM

- Monthly pilot country CoP sessions: Monthly meetings will be held for each country CoP to identify discuss and address oxygen gaps and challenges. Uganda, South Africa and Senegal CoPs will meet on the first, second and third Thursday of each month, respectively, if schedules permit. Preparation templates, containing guiding questions, will be shared in advance to help shape the agenda and collect data needed for troubleshooting with relevant ministries, agencies and other stakeholders.
- Next roundtables: The fourth and fifth GO<sub>2</sub>AL CoP roundtables are planned for Q2 and Q3 2026 to share progress and achievements of the pilot CoPs.
- Ongoing feedback: All CoP members are encouraged to continue sharing challenges, progress and potential solutions for the pilot country CoPs with the coordinating team. This input will inform both country-level activities and broader discussions.