Australia New Zealand Industrial Gas Association

Application for revocation and substitution of authorisation

September 2021

1. Executive Summary

On 1 October 2020, the ACCC granted conditional authorisation AA1000516-1 (the **Current Authorisation**) to Australia New Zealand Industrial Gas Association (**ANZIGA**). The Current Authorisation enables ANZIGA and its members, future members and their related bodies corporate and other suppliers of medical oxygen to hospitals and similar medical facilities in Australia that are notified to the ACCC by ANZIGA (collectively the **Parties**) to exchange information and make and give effect to contracts, arrangements and understandings to ensure security of supply of medical oxygen to hospitals and similar medical facilities during the COVID-19 pandemic (the **Authorised Conduct**). The Current Authorisation expires on 30 September 2021.

In its original application, ANZIGA stated *"It is not clear how long the COVID-19 pandemic will last, however authorisation for the Proposed Conduct is sought for a period of 12 months from the date of a final determination by the ACCC. It is possible that, if the pandemic lasts for longer than this, this period may need to be extended."*

To date, Australia has managed to limit COVID-19 infection rates to levels where security of medical oxygen supply has not been threatened. Consequently, the Parties have not needed to date to engage in the Authorised Conduct. If Australia can contain COVID-19 infection rates to current levels, the need to engage in the Authorised Conduct will hopefully not arise.

However, ANZIGA and its members are conscious that infection rates are currently growing in New South Wales and Victoria and the risk of outbreaks in other areas of Australia is high. ANZIGA is also conscious that, as at 1 September, 59.6% of people in Australia over the age of 16 had had at least one COVID-19 vaccine dose, and only 35.7% were fully vaccinated.[1] There is also a continuing risk that COVID-19 may evolve into new, more infectious strains. As a result of this, the risk of further waves of infections remain real.

It therefore remains critical for the medical gas industry to remain prepared should there be an escalation in medical gas demand.

For this reason, ANZIGA is seeking a revocation and substitution of the Current Authorisation. ANZIGA proposes that any new authorisation would be for for a further term of one year and would cover the same conduct and be subject to the same conditions as the ACCC authorised previously. This will preserve the ability of the Parties to respond if necessary to ensure security of supply of medical oxygen to hospitals and similar medical facilities if the COVID-19 pandemic escalates.

ANZIGA submits that authorisation of the proposed conduct is clearly in the public interest and that any potential public detriments are outweighed by the benefits associated with ensuring security of supply of medical oxygen.

In light of the need for the Parties to be able to respond quickly if the pandemic escalates, ANZIGA also seeks interim authorisation for the period until the ACCC has granted final authorisation.

[1] https://www.health.gov.au/sites/default/files/documents/2021/09/covid-19-vaccine-rollout-update-1-september-2021_0.pdf

2. Application for revocation and substitution of authorisation

2.1 Applicant

The Australia New Zealand Industrial Gas Association (**ANZIGA**) is the peak industry body representing companies that produce and distribute industrial gases, including bulk and compressed gas for the industrial, medical, food, scientific and hospitality markets in Australia and New Zealand. ANZIGA provides advice and guidance for its members to maintain the highest level of safety and concern for the environment and the community.

The current full members of ANZIGA (**Members**) are:

(a) Air Liquide Australia Limited (**Air Liquide**);

(b) BOC Limited (**BOC**); and

(c) Coregas Pty Ltd (**Coregas)**.

2.2 Application

ANZIGA requests that the ACCC revoke authorisation AA1000516-1 (the **Current Authorisation**) which was granted on 1 October 2020.

The Current Authorisation will expire on 30 September 2021. ANZIGA on behalf of:

(a) itself;

(b) its members, future members and their related bodies corporate[2]; and

(c) any other suppliers of medical oxygen to hospitals or similar medical facilities in Australia notified to the ACCC from time to time by ANZIGA,

applies for the Current Authorisation to be revoked and substituted with a new authorisation to engage in the conduct described in section 5 of this submission (**Proposed Conduct**) in order to ensure security of supply of medical oxygen to hospitals and similar medical facilities.

ANZIGA also applies for interim authorisation for the Proposed Conduct, as set out at section 7 of this submission.

2.3 Term of authorisation

It continues to be unclear how long the COVID-19 pandemic will last, however authorisation for the Proposed Conduct is sought for a period of 12 months from the date of a final determination by the ACCC. It is possible that, if the pandemic lasts for longer than this, this period may need to be further extended. Alternatively, should the effects of the pandemic abate before the end of this proposed period, ANZIGA and the Members consider that this would constitute a material change of circumstances that would enable the ACCC to review and, if appropriate, revoke the authorisation at an earlier date pursuant to its powers under section 91B of the CCA.

[2] For the purposes of this application, related bodies corporate has the meaning set out in section 4A of the CCA.

2.4 Confidentiality

Information in support of the application for authorisation is set out in these submissions. The confidential version of these submissions contains a range of information that is confidential and competitively sensitive. Disclosure of this information could result in material financial loss and prejudice the competitive position of the Members. Accordingly, ANZIGA and the Members request pursuant to section 89(5) of the CCA that this information be kept confidential by the Commission. For convenience, in the confidential version of this submission this information is indicated by the use of bold red parentheses (**[ ]**) around confidential text. .

2.5 Contact person

Correspondence in relation to this application should be addressed to:

Kathryn Walton
Executive Officer, ANZIGA
Level 11, 10 Queen Street, Melbourne, Victoria, 3000
Ph:
Email:

3. Background

3.1 Medical Oxygen

One of the gases produced and supplied by the Members is oxygen used for medical purposes in hospitals or other healthcare facilities, otherwise referred to as '**medical oxygen**'.

Medical oxygen is used in healthcare in a wide range of applications. It is crucial for the treatment of COVID-19 patients in the most severe respiratory distress. It is used in high volumes to support life when patients are being ventilated in Intensive Care Units (**ICUs**), and in lower volumes to support patients at other stages of the disease. Medical oxygen is also a lifesaving treatment for patients suffering from other life-threatening illnesses and is used to support life for patients undergoing surgery. Medical oxygen is also used to support patients with respiratory diseases at home, supplied via cylinders or stationary or portable oxygen generators called concentrators.

On 4 April 2020, the World Health Organisation issued a guidance note entitled *Oxygen sources and distribution for COVID-19 treatment centres* which discusses the use of oxygen in the treatment of COVID-19 and issues in ensuring secure supply (**WHO Guidance Note**). A copy of the WHO Guidance Note is annexed to this application at Annexure C.

3.2 Oxygen production

Medical oxygen is produced by liquefying air in large plants called Air Separation Units (**ASUs**) which then split the liquid into its component parts, including oxygen, nitrogen and argon. ASUs produce both medical oxygen and oxygen for industrial purposes (as well as other gases). It is estimated that medical oxygen accounts for in the order of 10% to 15% of

total oxygen demand. The remaining 85% to 90% of oxygen production is used for industrial purposes such as the following:

(a) in combustion processes in manufacturing to achieve the high temperatures necessary to manipulate metals and glass or to manufacture cement (otherwise known as 'oxy-fuel combustion processes');

(b) in welding and metal cutting procedures;

(c) in food industries, where it is used in the transportation of live fish and seafoods or to extend the shelf life of packaged foods in the form of 'modified atmospheric packaging'; and

(d) in sewage treatment, where it is used to support the bacteria used in treating and stabilising the wastewater.

ANZIGA Members operate ASUs and supply a number of wholesale suppliers who then re-supply oxygen in gas cylinder form to industrial customers. The Members also understand that Supagas Pty Ltd (**Supagas**), which is an associate member of ANZIGA, has an ASU in Victoria which it uses to supply industrial oxygen and some medical oxygen, and further ASUs used to supply purely industrial customers. Nevertheless, the Members estimate that, in combination, they would supply over 90% of oxygen to end users and would account for the supply of nearly all medical oxygen. Oxygen is mainly produced locally because it is not economically feasible to import large quantities of this gas into Australia.

ASUs represent a multi-million dollar investment and typically this is supported by a major customer who contracts a significant proportion of the ASU production capacity, with revenue from merchant sales to other customers supporting the investment case. Sometimes these arrangements include the major customer agreeing to supply utilities (such as power, gas, steam, air and water) in exchange for product supply (an **anchor** customer). In some cases, if the operations of these anchor customers were to be affected by COVID-19, there is potential for production of medical oxygen at the associated ASU to be affected.

The table below shows the locations of Members' ASUs that are currently used to supply medical oxygen, and whether each is operationally interdependent with an anchor customer in the sense described above.

ANZIGA Member	Location	Interdependent with anchor customer as defined above
BOC	Port Kembla, NSW	[redacted]
	Bulwer Island, Queensland	
	Townsville, Queensland	
	Dandenong, Victoria	
	Whyalla, South Australia	
	Kwinana, Western Australia	

ANZIGA Member	Location	Interdependent with anchor customer as defined above
	Lutana, Tasmania	[redacted]
Coregas	Port Kembla, NSW	
	Mackay, Queensland	
Air Liquide	Kwinana, Western Australia	
	Port Pirie, South Australia	
	Altona, Victoria	
	Botany, NSW	

3.3 Forms of supply

Once produced in ASUs, medical oxygen can be supplied to hospitals and healthcare facilities in two ways:

(a) In bulk liquid form; or

(b) In gaseous form, provided in reusable cylinders.

Bulk supply

Most medical oxygen is supplied to hospitals in bulk liquid form, where it is supplied to storage facilities called Vacuum Insulated Evaporators (**VIE**) or 'bulk vessels with vaporisers'). From there it is reticulated through pipelines to fixed outlets - usually at patients' bedsides or in operating theatres. This is the most common form of supply to administer oxygen to stationary patients.

Supply in cylinders

In addition to supply in bulk form, medical oxygen can be supplied in reusable cylinders specially designed for the safe storage, transport and use of medical oxygen in its gaseous form. In a medical context, this form of supply is mostly used for mobile applications such as in ambulances, or in other circumstances where a fixed pipeline supply is not available.

If temporary hospital wards were required to be established in Australia to treat COVID-19 patients (such as has been required in other countries), these may be equipped with either a bulk VIE storage, manifolded cylinder packs or compressed gas cylinders, depending on needs and purpose (i.e. ICU expansion or overflow for less critical patients). The potential use of such wards could therefore result in an increased demand for medical oxygen in gas cylinder form.

3.4 Contractual supply arrangements

ANZIGA and the Members expect that any increase in demand for medical oxygen will be focussed in the public hospital system, as this is where high acuity COVID-19 patients will be treated.

In New South Wales, Queensland and Victoria, oxygen is supplied to public hospitals pursuant to tender or RFP processes run by each state health department. The head agreement concluded as a result of the tender process will govern the prices for supply of medical oxygen in each state. In Queensland, the Department of Health has appointed two suppliers of medical gas to the state's public hospitals and allocated public hospitals between the two suppliers. In New South Wales, the Department of Health has divided the state into Local Health Districts. Under this system, the Department of Health selects a supplier which is responsible for supplying oxygen to all public hospitals in each district. In Victoria, individual public hospitals arrange supply with individual suppliers pursuant to the overarching terms of the state head agreement.

In each of South Australia, Western Australia, the Northern Territory, Australian Capital Territory and Tasmania, the relevant state or territory government has appointed a single contracted supplier of medical oxygen to all public hospitals in the state.

In some cases, medical oxygen in gas cylinder form may be used in the homes of patients receiving home-based treatments. Where this occurs, the oxygen will be supplied pursuant to the treating hospital's supply arrangements. The relevant gas cylinders may either be taken from the hospital's stock and delivered with the ambulance that takes the patient home, or the hospital may arrange for its supplier to deliver oxygen cylinders direct to the patient's home. Cylinders can also be supplied to the home either directly by a Member or by one of their distributors.

4. Potential threats to supply

4.1 Overview

Australia has managed, to date, to limit COVID-19 infection rates to a level where security of medical oxygen supply has not been threatened. Nevertheless, there continues to be potential for a large increase in demand for medical oxygen as a result of the pandemic, primarily due to the potential for increase of patients requiring ventilation support in hospitals and healthcare facilities.

The WHO Briefing Note observes that "*The ability to boost capacity to deliver oxygen therapy is the cornerstone of the overall approach to managing the COVID-19 outbreak and it has implications for the functioning of the entire system.*"[3]

ANZIGA and the Members do not believe that there is currently any indication that the demand for medical oxygen will exceed overall production or supply capacities. Nevertheless, there is a potential for the COVID-19 pandemic to result in both:

(a) rapid increases in demand for oxygen in localised geographic areas that can't be predicted with certainty; and

[3] WHO Briefing Note at P3

(b) at the same time, disruptions to elements of the supply chain.

The Members therefore foresee that there could be circumstances in which they may need to coordinate in order to ensure security of supply of oxygen to hospitals and other medical facilities. Should such a situation arise, the Members wish to be in a position to respond without concern that a coordinated response may contravene competition laws.

4.2 Potential increase in demand for oxygen.

There is evidence that the COVID-19 pandemic has led to large increases in demand for medical oxygen in foreign markets. For example, the European Industrial Gases Association (**EIGA**) indicated in its March 2020 briefing note that, even at this early stage of the pandemic, some manufacturers and suppliers had registered medical oxygen demand increases of five to tenfold.[4] The Wall Street Journal has noted the following in respect of respiratory ventilators and the supply of medical oxygen:

> "*Most anxiety over respiratory treatment during this pandemic has centred on shortage of ventilators. But respiratory therapists rely on purified medical oxygen delivered to patients through those devices. Supplying enough oxygen to meet soaring demand is critical and may prove complicated.*"[5]

Further, the Therapeutic Goods Administration (**TGA**) has released a publication noting the following:

> "*it is anticipated that there will be a surge in the number of patients requiring respiratory support, and there may be a shortfall in the number of devices available, that are intended to ventilate these patients*".[6]

Plainly, an increase in demand for ventilators will lead to an increase in demand for the medical oxygen used with such ventilators. To some extent, this increase in demand has already been realised. For example, New South Wales public hospitals have quadrupled their numbers of intensive care unit beds and ventilators since 2020 levels[7]. On 30 August 2021, it was reported that in the previous 12 days active COVID cases in New South Wales had almost doubled and the number of patients on ventilators had nearly doubled in the previous week.

4.3 Nature of demand increases

Localised/regional demand spikes

Overseas experience shows that increases in demand for medical oxygen is unlikely to be evenly distributed. Instead, it is likely that COVID-19 outbreaks, and therefore any increases in demand for medical oxygen, are likely to be focussed in particular regions. The city of Bergamo in Italy and New York in the United States were early examples of this.

Here in Australia, it can be seen that the COVID 19 cases being observed in New South Wales as at the date of this application are not evenly distributed, but are instead heavily

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4 See: https://www.ft.com/content/013d3bb8-5d4a-4cac-a53f-5eb44303d6eb . A full copy of the EIGA briefing note can be found at Confidential Annexure D.

5 Full article available at: https://www.wsj.com/articles/gas-suppliers-face-soaring-demand-for-oxygen-to-treat-coronavirus patients-11585223338

6 Media release available at: https://www.tga.gov.au/covid-19-information-clinicians-ventilators-and-alternative-strategies-when-short-supply

7 **https://thewest.com.au/news/coronavirus/nsw-breaks-aust-record-with-825-new-cases-c-3745516**

concentrated around the Nepean, Liverpool and Westmead public hospitals, with further concentrated outbreaks around Dubbo and the small centre of Wilcannia.

Potential changes in form of demand

Medical oxygen is normally supplied to hospitals and healthcare facilities in bulk liquid form. However, to respond to outbreaks of COVID-19, healthcare providers in other countries have had to create temporary hospitals. These facilities have adapted existing buildings, such as hotels or stadiums, for medical purposes. For example, the NHS Nightingale Hospital set up inside the National Exhibition Centre in Birmingham (United Kingdom) had a capacity for up to 2000 beds.[8]

Temporary facilities are also likely to be a feature of Australia's response to COVID 19 outbreaks. The New South Wales, Victoria and Queensland governments have planned for temporary healthcare facilities in vacant hotels, convention centres, mining camps and fields. As at the date of this application, both Sydney's Westmead and Blacktown hospitals had been forced to erect tents to create room to screen and swab patients to help manage capacity[9]

Such facilities may not have the bulk storage vessels and fixed supply pipelines necessary to distribute oxygen supplied in bulk liquid form. It is therefore likely possible that medical oxygen in such facilities may need to be supplied in gas cylinders rather than in bulk. This creates a potential for substantial increases in demand for medical oxygen in gas cylinder form.

4.4 Production constraints

The Members believe that, in total, Australia has more than adequate production capacity for any anticipated demand nationally. However, as described in section 3.2 above, some of the Members' ASUs may be operationally linked with the operations of 'anchor' customers. If the operations of these customers were to be affected by COVID-19, there is potential for production of medical oxygen to be affected.

The supply of medical oxygen is also dependent on the availability of a highly trained workforce. The Members have each had to consider a scenario where a COVID-19 outbreak at a production or distribution facility could cause its temporary closure or cause a lack of availability of appropriately trained and experienced personnel. In such circumstances, although each Member has contingency plans in place to mitigate this risk (including remote operation capability at some sites), the relevant ASU may nevertheless be forced to close for a period in order to contain the outbreak. It is also possible that a Member could have an outage at an ASU for any of a range of other reasons that might affect that Member's ability to produce medical oxygen in a particular region.

When a Member suffers an outage at one of its ASUs, and stored product at that site falls below acceptable levels, it is not unusual to transport oxygen from another state to cover the lost production. However, if such an outage were to occur at a time of high demand and/or a time when transportation of goods might be restricted due to COVID-19 restrictions, then this may not be possible.

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8 See https://www.bbc.com/news/health-52125059 , which indicates that according BDP Principal (the company that helped convert the National Exhibition Centre to a hospital) one of the top 3 challenges was "being able to get medical gases to each of the beds" and that required installation of "temporary generators and oxygen tanks to supply the beds" (i.e VIEs). See also: https://www.bbc.com/news/uk-england-52245254

9 https://www.reuters.com/world/asia-pacific/sydney-hospitals-erect-emergency-tents-amid-delta-surge-2021-08-25/

4.5 Supply of medical oxygen cylinders

Each Member has a limited number of medical oxygen cylinders that are in constant circulation between the production site, where they are filled, and the customer site, where the gas is used and the empty cylinders are collected for refilling.

The WHO observes that "*when cylinders are the only source of oxygen in a health facility, a strong supply-chain is required to ensure ongoing availability*".[10] Globally, a number of countries have experienced shortages of medical oxygen cylinders as the pandemic has increased demand for medical oxygen in this form.[11]

The number of cylinders currently owned by each Member is sufficient to meet normal demand. However, as noted above, there is potential that COVID-19 could result in a disproportionately high increase in demand for medical oxygen in gas cylinders. In a period of rapidly increased demand, the number of cylinders available to a Party in any area may become inadequate.

The ability to simply add more cylinders is limited by the fact that cylinders are currently in high demand globally, there is currently no local manufacturing of cylinders in Australia and it is unlikely that this capability could be created in the short term. Acquiring new cylinders therefore involves long international supply chains that have been exacerbated by the current COVID-19 pandemic and related commercial disruption. This means that there could be substantial lead times to acquire more cylinders.

The supply of medical oxygen in gas cylinders is also heavily regulated in regards to safety and product specification requirements.

Additional constraints on the ability to supply medical oxygen in cylinders include the fact that cylinders returned from hospitals or other medical facilities in COVID areas of concern may need to be thoroughly sanitised before they can be refilled - otherwise the cylinders themselves present a risk for transmission of COVID-19 or other bio-hazards. At various times during the pandemic the Members have had to implement more rigorous sanitisation processes, which further slows the cylinder filling process. The capacity of cylinder filling centres is also constrained by the number of healthy, trained and qualified cylinder fillers available.

All of these constraints, combined with the potential for spikes in demand for medical oxygen in gas cylinders to be focussed in particular areas, create the potential that a Party may be unable to supply the demand for medical oxygen in gas cylinder form from its contracted customers in a particular area. If this were to occur, the affected Party may need to ask the other Parties to assist with supply of medical oxygen to the relevant hospital, healthcare facility or region.

4.6 Transportation and logistics

Even for medical oxygen supplied in bulk form, the capacity for Parties to respond to increased demand for medical oxygen has potential to be constrained by the following issues:

(a) Each Member has a limited number of specially designed trucks capable of delivering medical oxygen from their respective ASUs to distribution centres and from there to customers including hospitals or healthcare facilities in each state.

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10 WHO Guidance Note at P2

11 eg, see: https://www.abc.net.au/news/2021-04-29/pandemic-medical-oxygen-coronavirus-what-is-it/100103684

(b) As demand for medical oxygen increases, so too will the number and frequency of deliveries required to each hospital.

(c) If the use of home treatments increases and/or if field hospitals are used, these increases in deliveries of bulk liquid oxygen may need to be accommodated simultaneously with a need to deliver an increased volume of oxygen in gas cylinder form to a range of new locations.

(d) Deliveries from within a relevant region are constrained by issues such as the number of available drivers and number of hours a driver can be on duty for in order to manage fatigue. In particular, in the case of bulk deliveries of medical oxygen, these trucks must be driven by specially qualified persons who receive specific training in relation to the particular hazards associated with liquid oxygen and the process of filling a hospital bulk vessel. It is estimated by the Members that it may take up to 10 weeks for a truck driver to obtain the relevant dangerous goods and cryogenic training and qualifications required to transport bulk medical oxygen.

(e) Deliveries from outside a relevant region may be constrained by issues such as the number of hours a driver can be on duty for in order to manage fatigue and border controls insofar as they may exacerbate additional delivery times, particularly as interstate travel restrictions become more stringent.

(f) As noted above, there is potential for the transportation and bulk filling workforce of any Party to be affected by concentrated outbreaks of COVID-19 which could require staff to be placed into quarantine or even cause the temporary closure of a Party's production and distribution facility.

When these constraints are considered in combination with the facts that:

(i) increases in demand for medical oxygen are likely to be focussed in particular areas or regions; and

(ii) contracts to supply medical oxygen in is likely to be held primarily by one or other of the Parties,

it is foreseeable that a Party may need to ask other Parties to assist with supply of medical oxygen in an affected area or region.

5. Proposed Conduct

5.1 Need for authorisation

Should the Members be confronted with any of the threats to supply described in section 4, their first response will be to:

(a) in the case of the public health system, inform and consult with the relevant State Health Department; and/or

(b) seek to negotiate bilaterally with another Party to purchase more oxygen.

Alternatively, in the event of supply challenges faced by one Party, it is possible that an affected customer or State Health Department may approach an alternative supplier directly.

ANZIGA and the Members can foresee, however, that not all issues may be able to be resolved through discussions of this type.

The Members consider that, if there were to be an increase in demand for medical oxygen in a particular region due to an outbreak of COVID-19 in that region, the most likely issue to arise would be a strain on the delivery logistics of the primary supplier in that region due to limited vehicles, a limited number of appropriately trained staff to carry out deliveries and limited storage facilities at each hospital.

Less likely, but still potentially a risk, is a shortage of available supply from the ASU of the primary supplier in that region due to increased demand for medical oxygen. Whilst it is unlikely that there would be an aggregate shortage of product at all ASUs in the region, there would likely be a strain placed on a supplier's logistics if required to source product from either its interstate plant or from another supplier's ASU in the region in which it has a shortage. Whilst delivery from other regions is possible, there would be a lengthened supply chain due to long haul distances.

Further, unplanned maintenance shutdowns do occur from time to time and, during a period of COVID-19 increased demand, for the logistical reasons already explained, it may be more difficult for a supplier to maintain supply continuity through such a shutdown by transporting product from its ASUs in other regions.

Another possible scenario, although less likely, is that the primary supplier to public hospitals in a region could suffer a COVID-19 outbreak among its staff at its ASU or distribution facility such that the supplier might be unable to meet demand for deliveries in the relevant region.

If any of the above were to occur, the logistics of scheduling a high number of deliveries across a potentially large number of sites with limited vehicles and a limited number of appropriately trained staff may require the Parties to share information and jointly plan the most efficient way to secure supply.

ANZIGA and the Members are concerned that such discussions could technically constitute an agreement to allocate customers within the meaning of section 45AD(3)(i) of the CCA or to allocate areas of supply within the meaning of section 45AD(3)(iii). ANZIGA and the Members are also concerned that the arrangements or the sharing of demand and supply information (even if that information relates only to a temporary situation caused by a short term spike in demand driven by COVID-19) could raise concerns under section 45(1) of the CCA.

5.2 Description of conduct to be authorised

In order to ensure that they can respond to the risks identified above and ensure continuity and security of supply of medical oxygen to hospitals and similar medical facilities, ANZIGA and the Members seek continued authorisation for the Parties to:

(a) exchange information in relation to each Party's:

(i) available stocks of;

(ii) anticipated demand for, and ability to supply

medical oxygen in either bulk liquid of gas cylinder form. This may include, for example, disclosing the identity, location and immediate requirements for medical oxygen of particular customers.

(b) make and give effect to contracts, arrangements or understandings as the Parties reasonably consider necessary to ensure the continuity and security of supply of medical oxygen to hospitals and similar medical facilities during the pandemic, including:

(i) restricting the supply of oxygen to customers other than hospitals and similar medical facilities;

(ii) determining who should supply particular hospitals or similar medical facilities;

(iii) coordinating the delivery of medical oxygen to particular areas or to particular hospitals or medical facilities; or

(iv) otherwise coordinating between the Parties to ensure that medical oxygen can be supplied in the most efficient manner possible so as to reduce the risk of an inability to supply any hospital or similar medical facility,

(together, the **Proposed Conduct**)

5.3 Conditions of authorisation

ANZIGA proposes that any new authorisation of the Proposed Conduct would be subject to the same conditions as apply to the Current Authorisation, as follows:

(a) After identifying a particular threat to the supply of medical oxygen and prior to engaging in the Proposed Conduct in relation to that threat, ANZIGA and the Members must give the ACCC written notice that:

(i) states that they have identified a threat to the supply of medical oxygen;

(ii) describes, in general terms, the nature of that threat and the geographic area affected;

(iii) states whether:

(A) where the threat affects the public health system—the relevant State or Territory health authority has been informed of the threat

(B) ANZIGA and the Members consider that the identified threat is unable to be managed by way of bilateral supply arrangements for the supply of medical oxygen to either the relevant State or Territory health authority or one or more of the Parties and, if so, a brief submission outlining the basis for this view including substantiating information, and

(C) ANZIGA and the Members consider it reasonably necessary to engage in the Proposed Conduct for the purpose of addressing the threat identified.

(b) The Parties must:

(i) provide regular updates to the ACCC in a form and at a frequency agreed between the Parties and the ACCC; and

(ii) provide to the ACCC, within a reasonable time period, all information and documents requested by the ACCC.

(c) All confidential or competitively sensitive information exchanged pursuant to the authorisation shall be used by the Party to whom it was provided solely for the purposes of ensuring the supply of medical oxygen to hospitals and similar medical facilities that might otherwise be at risk of disruption as a result of the impacts of COVID-19.

6. Public benefits and detriments of the Proposed Conduct

6.1 Public benefits

A 'public benefit' has been defined as "*anything of value to the community generally, any contribution to the aims pursued by the society including as one of its principal elements (in the context of trade practices legislation) the achievement of the economic goals of efficiency and progress*".[12]

The World Health Organisation (**WHO**) stated in its Situation Report 41 that "*Oxygen therapy is the major treatment intervention for patients with severe COVID-19. All countries should work to optimise the availability of pulse oximeters and medical oxygen systems*".[13]

The Proposed Conduct has the sole purpose of ensuring that the Parties are able to ensure supply of medical oxygen to hospitals and healthcare facilities during the COVID-19 crisis. This, in turn, ensures that those hospitals and similar facilities are able to provide life saving treatments that depend on the availability of medical oxygen. If the Parties were unable to ensure supply of medical oxygen to hospitals and healthcare facilities during the COVID-19 crisis, this could directly result in significant loss of life. ANZIGA and the Members therefore submit that the Proposed Conduct is likely to result in a public benefit of the highest order.

6.2 Public detriment

ANZIGA and the Members submit that the Proposed Conduct is unlikely to result in any public detriment. In particular, ANZIGA and the Members note the following:

(a) the Proposed Conduct will not extend to arrangements or understandings in relation to the prices of supply of affected products; nor will it extend to or have any impact on the Parties' terms of supply after the COVID-19 crisis has abated;

(b) the Proposed Conduct is not likely to materially alter the competitive dynamics in any market and, to the extent that are any short-term competitive effects, those effects will not extend beyond the period of any COVID-19 related supply shortages;

(c) the Members intend only to rely on the ability to make contracts, arrangements or understandings pursuant to the authorisation where other arrangements, such as bilaterally negotiated supply agreements between the Parties, appear likely to be inadequate to address the perceived threat to supply;

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12 *Victorian Newsagency* (1994) ATPR 41-357 at [42,677].

13 Report available at: https://www.who.int/docs/default-source/coronaviruse/situation-reports/20200301-sitrep-41-covid-19.pdf?sfvrsn=6768306d_2

(d) the ACCC will be in a position to exercise oversight of the conduct as ANZIGA and the Members will keep it updated of contracts, arrangements or understandings that are reached pursuant to the authorisation and the reasons for those contracts, arrangements or understandings.

ANZIGA and the Members therefore submit that the likely public benefits of the Proposed Conduct would be likely to greatly outweigh any potential public detriment.

7. Application for Interim Authorisation

The unpredictable nature of the COVID-19 pandemic means that there is a potential for demand to increase and for any of the potential threats to supply outlined in section 4 of this application to eventuate before such time as the ACCC has the opportunity to complete its usual authorisation process. Accordingly, ANZIGA and the Members request that the ACCC grant interim authorisation as soon as practicable.

Annexure A Details of and declaration on behalf of Applicant

Details of Applicant

Name:	Australia New Zealand Industrial Gas Association
Address (registered office):	Level 11, 10 Queen Street, Melbourne, VIC 3000
Telephone number:	
ACN:	003 067 178

Declaration on behalf of Applicant

The undersigned declares that, to the best of their knowledge and belief, the information given in this submission is true, correct and complete, that complete copies of documents required by this form have been supplied, that all estimates are identified as such and are their best estimates of the underlying facts, and that all the opinions expressed are sincere.

The undersigned undertakes to advise the ACCC immediately of any material change in circumstances relating to the application.

The undersigned is aware of the provisions of sections 137.1 and 149.1 of the Criminal Code (Cth).

Signature of authorised person

Executive Officer

Office Held

Kathryn Walton

Name of authorised person

This 13th day of September 2021

Annexure B Contact details for ANZIGA and the Members

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Annexure C World Health Organisation Guidance Note

Oxygen sources and distribution for COVID-19 treatment centres

Interim guidance

4 April 2020

World Health Organization

Background

This is interim guidance on oxygen sources and distribution strategies for COVID-19 treatment. It has been adapted from WHO and UNICEF's technical specifications and guidance for oxygen therapy devices, which is part of the WHO *medical device technical series*,[1] and is based on current knowledge of the situation in China and other countries where cases have been identified.

This guidance is intended for health facility administrators, clinical decision-makers, procurement officers, planning officers, biomedical engineers, infrastructure engineers and policy-makers. It describes how to: quantify oxygen demand, to identify oxygen sources that are available, and select appropriate surge sources to best respond to COVID-19 patients' needs, especially in low-and-middle income countries. WHO will update these recommendations as new information becomes available.

COVID-19 and oxygen

Data from China suggests that although the majority of people with COVID-19 have mild illness (40%) or moderate illness (40%); about 15 % of them have severe illness requiring oxygen therapy, and 5% will be critically ill requiring intensive care unit treatment. In addition, most critically ill COVID-19 patients will require mechanical ventilation.[2,3] For these reasons, COVID-19 treatment health-care facilities should be equipped with pulse oximeters, functioning oxygen systems including single-use oxygen delivery interfaces.[4]

Oxygen therapy is recommended for all severe and critical COVID-19 patients, with low doses ranging from 1-2 L/min in children and starting at 5 L/min in adults with nasal cannula, moderate flow rates for use with venturi mask (6-10 L/min); or higher flow rates (10-15 L/min) using a mask with reservoir bag. In addition, oxygen can be delivered at higher flow rates and in higher concentrations, using high-flow nasal cannula (HFNC) devices, non-invasive ventilation (NIV) and invasive ventilation devices.[4]

Compared with standard oxygen therapy, HFNC and NIV devices may reduce the need for intubation,[5] which may be a consideration in settings where there is limited availability of mechanical ventilation. However, HFNC and NIV devices. carry a risk of aerosol generation and thus requiring airborne precautions by the health workers using them.

CAUTION

- Oxygen supports combustion. The addition of concentrated oxygen to a fire increases its intensity considerably and can even support the combustion of materials that normally do not burn.
- Do not go near any open flames when using oxygen – Do not smoke near to oxygen sources!

Oxygen sources

Oxygen therapy or supplemental oxygen is the provision of medical oxygen as a health-care intervention. Medical oxygen contains at least 82% pure oxygen, is free from any contamination and is generated by an oil-free compressor. **Only high quality, medical-grade oxygen should be given to patients.**

Oxygen systems must consist of an oxygen source, or production combined with storage. Common oxygen sources are: oxygen generating plants and liquid oxygen in bulk storage tanks, and oxygen concentrators. The most common source of oxygen storage used in health-care settings is a cylinder.

The appropriate choice of oxygen source depends on many factors, including: the amount of oxygen needed at the treatment centre; the available infrastructure, cost, capacity and supply chain for local production of medicinal gases; the reliability of electrical supply; and access to maintenance services and spare parts, etc. Details about these different oxygen-source options are provided in this guidance, and in more depth in WHO-UNICEF *technical specifications and guidance for oxygen therapy devices*.[1]

Liquid oxygen plants: Cryogenically produced liquid oxygen is always generated off-site (not at a medical facility). Medical facilities can be equipped with large bulk liquid oxygen tanks that are refilled periodically by a truck from a supplier. The liquid oxygen tank supplies a centrally piped system throughout the health facility by self-vaporization and for which a power supply is not required. Although an economical option in some settings, the use of liquid oxygen relies on external supply chain mechanisms and needs a bit more caution with respect to transport and storage due to the risks associated with higher pressures. Extra care should be taken in more extreme environments. It is best practice to also have cylinders as a backup supply.[1]

PSA oxygen plant: A pressure swing adsorption (PSA) oxygen plant serves as a large, central source of oxygen generation using PSA technology (similar to concentrators) that can be located on-site at medical facilities.

Oxygen from a PSA plant can either be piped directly to bedside terminal units within patient areas or, with a booster compressor, be used to refill cylinders for oxygen distribution (either on-site or to neighbouring health facilities) or for

backup oxygen supply. Oxygen plants require a reliable source of power. It is best practice to also have cylinders as a backup supply.

Oxygen concentrators: An oxygen concentrator is a self-contained, electrically powered medical device designed to concentrate oxygen from ambient air. An oxygen concentrator uses PSA technology to draw in air from the environment, removing the nitrogen to produce a continuous source of more than 90% concentrated oxygen. It should not be used if the oxygen concentration falls below 82%.[1]

Oxygen concentrators are portable and can be moved between clinical areas, but they are also often set up to be stationary fixtures in patient areas. Concentrators designed for portable medical support are available in models that can deliver maximum flow rates of between 5 and 10 L/min.

When used with a flowmeter stand for splitting flow, concentrators can provide a continuous supply of oxygen to multiple patients at the same time. Concentrators can provide a safe and cost-effective source of oxygen, but they do require a source of continuous and reliable power and regular preventive maintenance to ensure proper functioning. It is best practice to also have cylinders as a backup supply.[1]

Oxygen storage and intra-hospital distribution

Oxygen cylinders: Oxygen gas can be compressed and stored in cylinders. These cylinders are filled at a gas manufacturing plant, either via a cryogenic distillation or a PSA plant,[6] and then transported to health facilities. Cylinders can be used in one of two ways. One, by installing them directly within patient areas or, similar to direct piping and two, by connecting them to sub-central manifold systems (groups of cylinders linked in parallel) at the facility. Thus, oxygen can be piped to specific areas of the health facility, even at the ward level. When cylinders are the only source of oxygen in a health facility, a strong supply-chain is required to ensure ongoing availability.

Once filled, cylinders themselves do not require electricity, but they do require several accessories and fittings to deliver oxygen, such as pressure gauges, regulators, flowmeters, and in some cases, humidifiers. Cylinders also require periodic maintenance, commonly provided by gas suppliers at the point of refilling.

Additionally, storage or transportation of medical oxygen in cylinders must be done carefully and by trained personnel as the contents are under extreme pressure.

Pipeline intra-hospital distribution networks are helpful to supply oxygen at high pressure to equipment such as anaesthetic machines and ventilators. A key advantage of pipeline systems is that they obviate the need for handling and transporting heavy cylinders between hospital wards. However, the high cost and complexity of installing centralized oxygen sources with copper pipelines and the associated specialized maintenance required for this make pipeline systems less accessible for turn-key installations.

Demand and supply

Given the global supply-chain issues resulting from the COVID-19 pandemic, WHO urges Ministries of Health to estimate their countries' oxygen needs and recommends using the WHO COVID-19 Essential Supply Forecast Tool (ESFT)[7] and other tools available at the WHO website: Essential resource planning including the WHO Biomedical Equipment Inventory Tool to determine existing oxygen sources and supply mix in order to leverage these for their COVID-19 response. Additionally, WHO urges Ministries of. Health to contact local oxygen producers and/or suppliers to benefit from locally available resources.

More information on oxygen sources is available in Table 2: Description and comparison of oxygen sources and storage.

Oxygen needs estimation

Another aspect of selecting the most appropriate source of oxygen is taking into consideration the gross flows of oxygen that will be needed for treatment. To determine the total flow needs, the anticipated case load has to be estimated. This can be done using the WHO COVID-19 Essential Supply Forecast Tool (ESFT).[7] From the total patients expected, the ratio of patient severity can be ascribed as outlined above: mild, moderate, severe or critical. Thus, the required flows can be estimated to meet the oxygen therapy needs for the hospitalized severe and critical patients, representing 20% of the total.

About 75% of the COVID-19 patients requiring hospitalization will be classified as "severe", and 25% as "critical". Thus, the total supply of medical oxygen required can be estimated based on the recommended flow rates for each patient severity category (shown in the Table 1 below).

Table 1: Sample oxygen flow planning per 100 bed facility

Hypothetical 100 bed COVID-19 treatment facility				
Disease severity	Avg. O_2 flow rate		Size of solutions of scale*	
	per patient	Total	PSA Plant	Bulk liquid
Severe 75 patients	10 L/min	75 * 10 * 60 = 45,000 L/hr	= 45 m^3/hr	= 1.25 m^3/day
Critical 25 patients	30 L/min	25 x 30 x 60 = 45,000 L/hr	= 45 m^3/hr	= 1.25 m^3/day
			= 90 m^3/hr	= 2.5 m^3/day

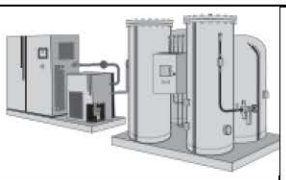
This sample scenario is based on a patient count. Typical quantification of this nature would be calculated based on availability of equipment. **It is important to re-assess needs once the equipment has been commissioned, as there are likely to be equipment-specific changes in demand.**

All assisted ventilation implies a mix of medical air and oxygen. Flows for critical patients indicated here represent only the oxygen portion of the total gas flow required to achieve target therapeutic fraction of inspired oxygen (FiO_2), which is the total % oxygen in the lungs available for gas exchange. FiO_2 will change over the course of a treatment, and vary from one patient to the next. The oxygen flow rate indicated here represents an average of the proportion of oxygen flows over the course of a patient's time on assisted ventilation. A simple equation to determine flow proportion at any time is as follows:

$$Target\ FiO_2 = \frac{O_2\ L/\min + (air\ L/\min\ x\ 21\%)}{Total\ flow, L/min}$$

The WHO COVID-19 ESFT[7] can also help to estimate other needs that will have to be included, such as ancillary devices, accessories, consumables and spares, etc. These tools and other associated documents can be found at WHO website: Essential resource planning.

Table 2: Description and comparison of oxygen sources and storage[1]

	Cylinders	Concentrators (PSA)	Oxygen plant (PSA)	Liquid oxygen
General characteristic				
Image				
Description	A refillable cylindrical storage vessel used to store and transport oxygen in compressed gas form. Cylinders are refilled at a gas generating plant and thus require transportation to and from the plant	A self-contained, electrically powered medical device designed to concentrate oxygen from ambient air, using PSA technology.	An onsite oxygen generating system using PSA technology, which supplies high-pressure oxygen throughout a facility via a central pipeline system, or via cylinders refilled by the plant.	Bulk liquid oxygen generated off-site and stored in a large tank and supplied throughout a health facility pipeline system. Tank requires refilling by liquid oxygen supplier.
Clinical application and/or use case	Can be used for all oxygen needs, including high-pressure supply and in facilities where power supply is intermittent or unreliable. Also used for ambulatory service or patient transport. Used as a backup for other systems.	Used to deliver oxygen at the bedside or within close proximity to patient areas. A single concentrator can service several beds with the use of a flowmeter stand to split output flow.	Can be used for all oxygen needs, including high-pressure supply.	Can be used for all oxygen needs, including high- pressure supply and in facilities where power supply is intermittent or unreliable.
Distribution mechanism	Connected to manifold of central/sub-central pipeline distribution system, or directly connected to patient with flowmeter and tubing.	Direct to patient with tubing or through a flowmeter stand.	Central/ sub-central pipeline distribution system, or can be used to refill cylinders that can be connected to manifold systems in the facility.	Central pipeline distribution system.
Electricity requirement	No	Yes	Yes	No
Maintenance requirement	Limited maintenance required by trained technicians.	Moderate maintenance required by trained technicians, who could be in-house.	Significant maintenance of system and piping required by highly trained technicians and engineers, can be provided as part of contract.	Significant maintenance of system and piping required by highly trained technicians and engineers, can be provided as part of contract.
User care	Moderate; regular checks of fittings and connections, regular checks of oxygen levels, cleaning exterior.	Moderate; cleaning of filters and device exterior.	Minimal; at terminal unit only.	Minimal; at terminal unit only.
Merits	– No power source.	– Continuous oxygen supply (if power available) at low running cost. – Output flow can be split among multiple patients.	– Can be cost-effective for large facilities. – Continuous oxygen supply.	– 99% oxygen obtained. – High oxygen output for small space requirement.
Drawbacks	– Requires transport/ supply chain. – Exhaustible supply. – Highly reliant upon supplier. – Risk of gas leakage. – Risk of unwanted relocation.	– Low pressure output, usually not suitable for CPAP or ventilators. – Requires uninterrupted power. – Requires backup cylinder supply. – Requires maintenance.	– High capital investments. – Requires uninterrupted power. Needs adequate infrastructure. – High maintenance for piping. – Requires backup cylinder supply. – Risk of gas leakage from piping system.	– Requires transport/ supply chain. – Exhaustible supply. – High maintenance for piping. – Needs adequate infrastructure. – Requires backup cylinder supply. – Risk of gas leakage from piping system.

Oxygen surge plan

The ability to boost capacity to deliver oxygen therapy is the cornerstone of the overall approach to managing the COVID-19 outbreak and it has implications for the functioning of the entire system. The principles, set out here, of building surge capacity should be integrated into a health system's readiness and response capacities for all functions – either centrally, or at facility level.[8]

Oxygen supply and delivery systems are limited in many resource-limited settings. Each supply option needs to be examined with attention to access and distribution. Liquid oxygen will accommodate great volumes; however, health systems must leverage existing facilities' operations where they exist (geographically). More localized (e.g. in-facility) PSA plants are an option, but if not already in-situ, there will be some lead-time for delivery and operationalization. With respect to bedside oxygen concentrators, these are a very tangible plug-and-play options, that are limited in terms of sheer volume that could be delivered.

Once the oxygen need has been estimated with the COVID-19 ESFT[7] and oxygen survey assessment have been completed, perform a rapid gap analysis. This means taking the estimated forecasted need and comparing this to existing oxygen supply availability. This method provides a way to identify a feasible, contextually appropriate oxygen surge strategy based on structures, capabilities, practices and technologies. Decision makers can then rapidly recommend next-steps, including product needs, that will help to frame and implement the surge plan.

The following describes different approaches, with key factors to be considered to help determine feasible and efficient solutions and expected impact. The oxygen surge plan should be integrated into the overall COVID-19 response plan. For instance, if a new COVID-19 treatment centre is planned, the location and layout of the construction site will be a key factor for the oxygen surge planning.

Liquid oxygen

1. Assess availability, locally and in neighbouring countries, considering importation and movements constraints.
2. Evaluate transport capacity, bulk tank availability, distances, road condition and security. NOTE: bulk tanks are supplier-specific. Smaller/ portable tanks are often readily available, but larger tanks for permanent installation must be ordered.
3. If bulk tanks are already in-situ at health facilities, assess storage capacity.
4. Evaluate capacity to vaporize liquid oxygen into gas, either with existing installations or as component on smaller/portable tanks.
5. Determine if gas can be piped directly to patients through an existing piping system or if it needs to be compressed into gas cylinders.
6. Ensure sufficient ancillary accessories, including valves and pressure and flow regulators.
7. Ensure sufficient medical devices for delivery oxygen therapy. Refer to WHO Essential resource planning.
8. Ensure sufficient resources (both HR and equipment) to carry out necessary maintenance.

Need quantification units: liquid oxygen for medical use is expressed in m^3 of liquid. Once the total flows are known, in L/min of gas, total volume of liquid can be determined over a specified period of time, using the following factor:

1 L of liquid oxygen = 861 L oxygen gas

1 m^3 = 1,000 L

PSA Plants

1. Assess if any plants are available and functioning locally, or if plants elsewhere nationally have any extra capacity.
2. PSA plants are designed to function 24 hours/day.

If available:

3. Maximize production capacity of PSA.
4. Augment transport capacity through excess supply via cylinders, when available. If not available, order appropriate quantity and type of cylinders.
5. Assess potential for installation of piping systems to optimize in-facility distribution (not a short-term solution).

If not available, assess local and international market for purchasing a plant according to specific context and needs. Details to consider:

a. Production quantity in m3/hr, booster pump for cylinder filling.
b. Delivery time.
c. Facility installation needs: housing for plant and filling ramp/manifold, cylinder3-phase electrical supply and reliability, cylinder storage.
d. Training and maintenance.

6. Ensure sufficient medical devices for delivery of oxygen therapy. Refer to the WHO website: Essential resource planning.
7. Ensure sufficient resources (both HR and equipment) to carry out necessary maintenance.

Need quantification units: PSA plants are sized according to output capacity, in m^3/hr, where m^3 is in oxygen gas. Once the total flows are known, in L/min of gas, total hourly flows can be calculated using the following conversion factors:

L/min * 60 min/hr = L/hr

L/hr *1m^3/1000 L = m^3/hr

Power essentials:

PSA plants rely on consistent, quality power.
A rule-of-thumb requirement is that 1.22 kWh ±5% of power is needed per m^3 of total flow.

It is imperative that the plant be connected to a reliable power supply along with voltage stabilization to avoid any interruption.

These are indicative requirements. Always consider manufacturer's technical specification for a more detailed power requirement estimation.

Bedside concentrators

1. Increase bedside oxygen concentrators in the immediacy, if supply permits, as complementary approach while waiting for higher-flow solutions to be delivered, such as a PSA plant or liquid oxygen capacity.
2. Once a PSA plant has been installed and commissioned, bedside concentrators can be used to increase geographical flexibility as they can easily be reallocated to other health facilities.
3. Ensure sufficient medical devices for the delivery of oxygen therapy. Refer to the WHO website: Essential resource planning
4. Ensure sufficient human resources and equipment to carry out necessary maintenance.

Power essentials:

Oxygen concentrators rely on consistent, quality power. A 10 L/min oxygen concentrator will require between 350-600 W, which is NOT variable with flows.

It is imperative that the plant be connected to a reliable power supply along with voltage stabilization to avoid any interruption.

All operations should be monitored and accompanied by diligent planned preventative maintenance activities. The use of logbooks is essential for documenting production and consumption. This will allow for optimization of resources and, where possible, further allocation of additional resources to support near-by health facilities with their COVID-19 response should there be any excess oxygen supply.

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Acknowledgements

This interim guidance draws extensively WHO-UNICEF technical specifications and guidance for oxygen therapy devices.[1] WHO thanks those who were involved in developing the report.

WHO continues to monitor the situation closely for any changes that may affect this interim guidance. Should any factors change, WHO will issue a further update. Otherwise, this interim guidance document will expire 2 years after the date of publication.

WHO reference number: WHO/2019-nCoV/Oxygen_sources/2020.1

Annexure D [redacted]