BRIEFING NOTE

Prepared by MGC BN 25/20 – March 2020

COVID-19 - Emergency Measures to Maintain Continuous Supply of Medical Gases

1. Introduction

EIGA member companies that are producing medical gases are deploying significant technical, human and financial resources in order to support the healthcare system to deal, in the most efficient way, the current emergency situation due to the spread of the COVID-19 pandemic. This can only be achieved with the cooperation of competent health authorities.

The WHO mentions in their situation report 41: "Oxygen therapy is the major treatment intervention for patients with severe COVID-19. All countries should work to optimize the availability of pulse oximeters and medical oxygen systems…"

Medicinal oxygen is an important drug used for patients with COVID-19 and therefore the availability of supply needs to be secured to patients throughout the healthcare system EIGA member companies have recently registered significant oxygen demand increase from hospitals from five to ten times higher than the usual consumption. Increased demand has also been reported for inhaled Nitric Oxide in hospitals treating severe COVID-19 patients.

EIGA proposes that members discuss with their National Gas Associations and National/Local Health Authorities to consider authorizing the following measures to alleviate the supply chain and better ensure the supply of all medical gases to hospitals and patients. All of the proposed measures are fully documented as per the Good Manufacturing Practice (GMP), including traceability and batch control, approved Quality Management System and entirely controlled by the Qualified Persons (QPs).

All the changes will be implemented in close communication and collaboration with competent authorities, customers and other stakeholders.

2. Situation prior to the COVID-19 pandemic

The medical gases manufacturers produce with a manufacturing licence under the Good Manufacturing Practice. Medicinal gases are marketed with a Marketing Authorisation (MA).

EIGA members confirm that these conditions remain in place and are adhered to. However, as result of the COVID-19 impact on the healthcare sector and the medical gases industry, primarily because of the huge need for medical oxygen for patients, EIGA proposes in section 4 some temporary measures for the duration of the COVID-19 pandemic.

3. Current encountered emergency issues in the supply of medical gases to the market

The following detrimental impact is occurring to the supply of medical gases to both healthcare facilities and homecare services:

- By far the largest and immediate impact is the exponential increase in demand of liquid medical oxygen, and gaseous oxygen cylinders;
- EIGA members have also noted increased demand for inhaled Nitric Oxide in certain hospitals that provide

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care for severe COVID-19 patients;

- The Qualified Persons, who have the responsibility to release each batch of medical product, need to be protected from the virus. However, several local/national rules prohibit the gases industry to apply more flexible conditions for the QPs to conduct their work;
- Operators and drivers working in medical gases manufacturing and distribution are critical to the supply of medical gases to healthcare facilities and patients. However, due to the spread of the coronavirus the medical gas industry is experiencing a severe lack of Personal Protective Equipment (PPE), e.g. respiratory masks, gloves and disinfectants;
- The number of patients at home increase significantly, and many of them need also medical oxygen supply or ventilator support. Due to the increased demand, initially primarily in hospitals, Home Oxygen and Home Ventilator systems are being ordered by national health authorities and hospitals to be used in healthcare facilities. This impacts homecare providers ability to ensure adequate care of existing home patients and it may severely restrict homecare for COVID-19 patients that could be discharged from hospitals.

4. EIGA proposed derogations to local/national regulations as temporary solution to the COVID-19 impact on supply of medical gases to healthcare system

EIGA members continue to comply with GMP rules and the conditions of the medicinal gases Marketing Authorisations (MA). Indeed, only medical grade oxygen shall be used and supplied for patients. All batches will remain under strict control and responsibility of the QP and each batch will be released as per the MA.

All equipment will continue to be verified to ensure safe and correct functioning for both operators and users.

New measures will only be applied after a full risk management assessment for the safety of staff, equipment, users and patients.

The following temporary measures are proposed by EIGA members in order to assure continuity of supply of medicinal gases and services, particularly medicinal oxygen to the healthcare system:

1. Allow the use of cylinders and cylinder bundles which are not listed in the Marketing Authorisation of the medicinal gas;
2. Allow to use active pharmaceutical ingredient and finished product from other manufacturing sites not listed in the MA, but with GMP certification;
3. Allow the installation of additional bulk liquid oxygen storage tank installations at hospitals and medical gases manufacturing facilities, verified on product quality, though without the need for prior local permits for installation;
4. Allow the increase of filling capacity of medical cylinders by installing or using additional filling equipment in medical gases manufacturing facilities, hence also increase the number of cylinders filled, without the need for prior local permits for installation and inspection or regulatory authorizations;
5. Allow the use of technical grade pressure, flow regulators and other gas administration accessories at healthcare facilities, which after risk assessment, are also verified on correct operation, because there is not enough of such medical grade equipment to provide to healthcare staff;
6. Allow a temporary one-year extension of service life of medical Valve Integrated Pressure Regulators (VIPR) (installed on a cylinder), to allow that more VIPR's can remain in the supply chain;
7. Allow a temporary one-year extension of service life of other CE-marked valves and regulators necessary in the administration of medicinal gases;
8. Allow 24/7 transport without restrictions of medical gases within the country and across borders, which is needed for optimal sourcing between production plants, in order to assure continuity of supply;
9. Allow the QP to release remotely and for multiple production sites listed in the MA, in order to provide flexibility and protection in working conditions to assure continuity of supply;
10. Allow the possibility to have only electronic delivery documents and avoid paper, hence protect the drivers.

EIGA is also working with national transport ministries on temporary derogations to dangerous goods transport regulations. There are already derogations for inspection of tankers and extending driver licences. A further derogation is being proposed to relax the test interval for gas cylinders.

EIGA proposes to allow these capacity upgrades by means of official derogation and limited in time to the duration of the crisis as assessed by the authorities, provided that all activities are all documented as per the Good Manufacturing Practice, (including traceability and batch control), approved Quality Management System, entirely

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controlled by the Qualified Persons and according to published good practices and safety standards. See the EIGA library for such industry standards and good practices.

At the end of the COVID-19 pandemic, which could differ in time per country, or upon request of the national/local competent authorities, EIGA members will stop the proposed temporary measures and re-instate the original requirements as per the GMP and MA requirements. Full communication with all stakeholders will be assured at all times.

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