WHITE PAPER

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GUARANTEEING HIGH QUALITY MEDICINAL GASES IN EUROPE

EIGA's view regarding the on-site preparation in healthcare facilities

Gaseous substances for inhalation by patients, such as oxygen and air, are usually supplied to healthcare facilities as licensed drugs in defined packages. The on-site production of medicinal gases by dedicated devices at hospital premises is also possible.

To ensure standard outcomes regardless of method for delivery, EIGA requests competent authorities provide harmonised guidance for the on-site production of medicinal gases in the forthcoming revision of the EU's General Pharmaceutical Legislation (GPL).

Risks to European Healthcare Systems

Without harmonised guidelines for the on-site production of medicinal gases, there are several risks for European healthcare systems:

- **Patient safety:** These products are continuously produced without the control and release by the pharmacist prior to being directly administered to patients. On-site medicinal gases production has limited quality assurance and a lack of quality surveillance.
- **Security of Supply:** Delivery of on-site produced medicinal gases can face supply issues linked to variable offtake demand, resulting in cessation of production due to fluctuating product quality. Other aspects relate to a heavy electrical dependency, plant maintenance issues and other plant failures, requiring an immediate back-up supply.
- **Liability for Healthcare Professionals:** Hospital pharmacists face increased liability as they are responsible for on-site production of medicinal gases, even if they are not directly involved. The lack of appropriate regulation results in legal uncertainty for all parties concerned, including the competent authority inspection.

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EIGA's recommendation for the European General Pharmaceutical Legislation

EIGA supports the revision of the EU General Pharmaceutical Legislation, of which the primary objective is to ensure timely and equitable access to safe, effective, and affordable medicines for all European patients.

EIGA requests the introduction of a clause in the Directive which calls for guidelines across EU Member States for on-site manufacturing of medicinal gases to ensure patient safety and maintain security of supply.

Amend the Directive by adding a new paragraph to Article 1 following Paragraph 6:

> ***Article 1 – Paragraph 6 a (new) Member states shall take measures to ensure that specific guidelines address the continuous on-site manufacturing of particular medicinal products, such as gases for medicinal use, when it is carried out in the hospital premises under the responsibility of the hospital pharmacist according to the exemption in paragraph, 5 point (b).***

About the European Industrial Gases Association
Founded in 1923, the European Industrial Gases Association (EIGA) is a safety and technically oriented organisation representing the vast majority of European and also non-European companies producing and distributing industrial, medical and food gases. EIGA itself does not produce or market industrial or medical gases or more information, visit www.eiga.eu or follow us on LinkedIn

EIGA represents 170 company members and national gas associations in 40 countries, in and outside Europe.

Even under a 10-fold increase of medicinal oxygen consumption during the COVID-19 pandemic, EIGA members continued to assure the supply of oxygen to healthcare.

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