Deliberation No ……/2025

Whereas:

Article 149(4) of Decree-Law No 176/2006 of 30 August, as amended, provides that the legal basis applicable to the primary or secondary packaging, labelling, information leaflet, technical management, transportation, distribution, marketing, supply and home distribution to patients of medical gases is defined by the regulations issued by INFARMED – Autoridade Nacional do Medicamento e Produtos de Saúde, I.P. [Portuguese Authority for Medicines and Health Products]. (INFARMED, I.P.).

The regulation on medical gases was approved by Decision No 56/CD/2008, of 21 February 2008, of the Executive Board of INFARMED, I.P., which entered into force on 1 March 2008.

Experience gained in the meantime, however, in the application of the Medical Gases Regulation, has recommended several amendments to the Regulation.

Thus, in accordance with Article 44(1) and (2) and Article 46 of the Code of Administrative Procedure, approved by Decree-Law No 4/2015 of 7 January 2015, and in accordance with Article 21(6) and Article 38 of the Framework Law on Public Institutes, approved by Law No 3/2004 of 15 January 2004, as amended, with Article 5(4) of Decree-Law No 46/2012 of 24 February 2012, as amended, which approved the organisation of INFARMED - Autoridade Nacional do Medicamento e Produtos de Saúde, I. P. (INFARMED, I. P.), with the Statutes of INFARMED, I. P., approved by Ministerial Implementing Order No 267/2012 of 31 August 2012, and amended in accordance with Ministerial Implementing Order No 306/2015, of 23 September, pursuant to Article 149(4) of Decree-Law No 176/2006 of 30 August 2006, as amended, the Governing Board of INFARMED, I.P., hereby rules as follows:

1 - The Medical Gases Regulation, approved by Decision No 56/CD/2008 of 21 February 2008 of the Governing Board of INFARMED, I.P., is repealed.

2 - The new Regulation on medical gases provided for in Article 149(4) of Decree-Law No 176/2006 of 30 August 2006, as amended, is hereby approved. It is annexed to and forms an integral part of this Decision.

3 - The best practices for the home distribution of medical gases referred to in Article 22 of this Regulation are set out in Annex I thereto.

4 - Entities which, on the date of entry into force of this Decision, are engaged in any of the activities provided for in the Medical Gas Regulation, as amended, shall have a period of one year to comply with the new provisions, in particular those relating to the technical management and good practices for the distribution of medical gases.

5 - Have been heard (...)

6 - This decision shall enter into force on the first working day of the month following its publication in the Official Journal of the Portuguese Republic.

XX XXXX 2025

The Governing Board

ANNEX

(Referred to in paragraph 2 of this Decision

REGULATION ON MEDICINAL GASES

Chapter I

General provisions

Article 1

Subject matter

This proposal for a regulation is intended to apply to the manufacture, primary or secondary packaging, labelling, information leaflet, technical management, transportation, distribution, marketing, supply and home delivery of the medical gases referred to in Article 149 of Decree-Law No 176/2006 of 30 August, as amended.

Article 2

Definitions

Without prejudice to the definitions contained in Decree-Law No 176/2006 of 30 August 2006, as amended, and in the other rules and principles of good manufacturing practice, for the purposes of this Regulation:

a) ‘Packaging’ means a cryogenic container, a tank, a tank, a cylinder, an assembly of cylinders or any other container which is in direct contact with the medical gas;
b) ‘Cylinder’ or ‘bottle’ means a transportable, pressurised tank with a maximum filling capacity of 150 litres of water;
c) 'Tank' means a tank fixed to a vehicle for the carriage of cryogenic or liquefied gas;
d) ‘Marketing’ means a set of operations carried out by the manufacturer, the marketing authorisation holder or the wholesale distributor for the purpose of supplying medical

gases to authorised entities for their purchase for resale or for administration;

e) 'Cylinder assembly' means an assembly of cylinders which can be coupled and interconnected by a distributor valve, for the purpose of transport and use as a unit;

f) ‘Contamination’ means the introduction into a given medical gas of a foreign substance of chemical, physical or microbiological origin;

g) ‘Cross-contamination’ means the contamination of a given medical gas by another medical gas or by the same gas at a different concentration;

h) 'Depressurisation' means the reduction of the pressure of a tank up to the level of atmospheric pressure;

i) ‘Home distribution of medical gases’ means the set of operations ranging from the supply to the home delivery of medical gases, including all operations carried out at the patient’s home aimed at the use of medical gases, from the handling of reservoirs and associated medical devices, to the preparation of cryogenic reservoirs;

j) ‘Domicile’ means the habitual residence or the place inhabited by the patient, where the medical gas is to be administered;

k) ‘Emptying’ means the vacuum removal of waste gas from a container;

l) ‘Supply or dispensation to the public’ means the pharmaceutical act associated with the supply of medical gases to the patient, in pharmacies, hospitals and public or private health services that have pharmaceutical services and other entities that meet the requirements laid down in this Regulation;

m) 'Gas' means a substance or a mixture of substances which are completely gaseous at 1,013 Bar (101,325 kPa) and + 15 °C or a vapour with a vapour pressure exceeding 3 Bar (300 kPa) at + 50 °C (ISO 10286);

n) ‘Bulk gas’ means an active substance used to produce a medicalgas, or medical gas which has not yet been packaged;
o) ‘Compressed gas’ means a gas which is completely gaseous when put up under pressure at -50°C;
p) 'Cryogenic gas' means a gas which is liquefied at 1.013 Bar at a temperature of less than -150 °C;
q) ‘Liquefied gas’ means a gas which is partially liquid (gas on liquid) when put up under pressure at -50°C;
r) ‘Medical gas’ means any gas or mixture of gases falling within the scope of Article 149 of Decree-Law No 176/2006 of 30 August 2006, as amended;
s) ‘Batch’ means the defined quantity of medical gas manufactured in an operation or series of operations in such a way that it can be considered as homogeneous;
t) ‘Batch number’ means the characteristic combination of numbers or letters or numbers and letters that specifically identifies a particular batch;
u) ‘Procedure’ means a description of the operations, precautions and measures to be implemented under the provisions of this Regulation;
v) 'Purging' means the action of emptying and cleaning a cylinder, performed by depressurisation and evacuation or by depressurisation, followed by partial pressurisation with the gas in question and new depressurisation;
w) ‘Cryogenic tank’ means a fixed or mobile, thermally insulated tank intended to contain cryogenic or liquefied gases, with the gas being removed in a gaseous or liquid state;
x) ‘Home cryogenic tank’ means a thermally insulated mobile cryogenic tank for home use of medical gas in gaseous form;
y) ‘Air separation’ means the process of purification, cleaning, compression, cooling, liquefaction and distillation that separated atmospheric air into oxygen, nitrogen and rare gases;

z) ‘Gaseous active substance’ means any gas which constitutes an active substance in a medicinal product;

aa) ‘Tank’ means a thermally insulated fixed cryogenic tank for the storage of liquefied gas or cryogenic gas;

bb) ‘Theoretical maximum residual impurity content’ means the amount of gaseous impurities, if any, present in the cylinders prior to the filling operation, which may originate from reflux and which remains after the pre-treatment operation. The calculation of this content is relevant only for compressed gases on the assumption that they act as perfect gases;

cc) 'hydrostatic pressure test' means a test carried out for safety reasons, in accordance with internationally defined standards, intended to verify the pressurisation capacity of the packaging material;

dd) 'Valve' means a device intended for opening and closing reservoirs, for the purpose of controlling the flow of gas;

ee) ‘Anti-return valve’ means the valve that allows flow in one direction;

ff) ‘Dispensing valve’ means a device or equipment intended to activate one or more gas tanks with a view to filling or emptying them simultaneously;

gg) ‘Minimum pressure check valve’ or ‘residual pressure valve’ means a valve equipped with a system that maintains a residual pressure above atmospheric pressure in the gas cylinder for the purpose of preventing contamination during use.

Chapter II
Manufacturing

Article 3
Manufacturing

The manufacture of medical gases is subject to the provisions of Decree-Law No 176/2006 of 30 August 2006, as amended, in accordance with the provisions of the European Guide to Good Manufacturing Practice for Medicinal Products and this Regulation.

Article 4
Authorisation

1 – The manufacture of medical gases is subject to authorisation by INFARMED - Autoridade Nacional do Medicamento e Produtos de Saúde, I.P., under the terms of the law.

2 – The manufacturing authorisation shall identify the filling sites and authorised manufacturing operations.

3 – In addition to the elements provided for in Article 56 of Decree-Law No 176/2006 of 30 August 2006, in its current wording and in the regulations approved under that Decree-Law, the application for authorisation provided for in paragraph 1 of this Article shall contain a list of the manufacturing sites and fixed tanks referred to in Article 6(2)(a), (b) and (c).

4 – The list referred to in the preceding paragraph, which must be kept and maintained at the disposal of INFARMED, I.P., must contain the following information:

a) The address of each location;
b) Identification of stored medical gases;
c) The type of existing fixed reservoirs and their quantity.

Article 5
Updating the authorisation

1 – Any changes to the manufacturing sites and fixed tanks referred to in Article 6(2)(a) and (b) shall be subject to the prior authorisation of INFARMED, I.P.

2 – Without prejudice to the previous paragraph, any changes to the list referred to in Article 4(3) shall be communicated to INFARMED, I.P., by 31 January of each year, to update the information contained in the authorisation, except in the case of changes with a possible impact on quality or safety, in which case the update shall be carried out immediately.

Article 6
Premises and equipment

1 – The premises of a medical gas manufacturer may include, in addition to the medical gas production premises, the premises of the manufacturer of the active substances and the medical gas filling points.

2 – The following shall be regarded as filling points for medical gases under the responsibility of the manufacturer:

a) Fixed tanks dedicated to the storage of medical gas in liquid form;
b) Fixed reservoirs made available to hospitals, public and private health services with pharmaceutical services or wholesale distributors;
c) The tanks used to supply the filling site and the fixed tanks serving hospital facilities, public and private health services with pharmaceutical services and wholesale distributors.

3 – Additional checks shall be carried out on the tank prior to filling, when the tank supplies other establishment or establishments of the same manufacturer, such as verification of the medical gas analysis certificate, in order to ensure the quality of the gas delivered, as well as to ensure effective traceability of medical gas and limit the risks of shortages in the case of collection of the batch.

4 – Fixed tanks shall comply with the legislation and standards applicable to the installation, operation, repair and alteration of pressure equipment.

Article 7
Packaging

1 – The packaging of medical gases and their essential safety accessories, such as safety valves, must comply with the appropriate technical specifications.

2 – Cylinders shall be fitted with minimum pressure check valves or, if fitted with other types of valves, shall comply with the specifications and carry out checks in accordance with Annex 6 to the European Guide to Good Manufacturing Practice in order to prevent contamination.

3 – The equipment referred to in the preceding paragraph must be dedicated to a single medical gas or a given mixture of medical gases.

Article 8
Labelling and package leaflet

1 – The labelling and package leaflet of medical gases shall comply, with the necessary adaptations, with the provisions of Article 104 et seq. of Decree-Law No 176/2006 of 30 August, as amended.

2 – In addition to the particulars required by the previous paragraph, the labelling shall also include the information contained in Annex 6 to the European Guide to Good Manufacturing Practice and in Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008.

Article 9
Traceability and registration

Manufacturers shall have in place appropriate traceability and collection systems for medical gases, as laid down for other medicinal products, and traceability systems for cylinders, mobile cryogenic containers and their valves shall co-exist.

Article 10

Technical management and staff

1 – Without prejudice to the application of the provisions of Article 60e and Article 202(5) of Decree-Law No 176/2006 of 30 August 2006, as amended, industrial production activities, in particular the transfer of the active substance or medical gas from a tank dedicated to the transport of a medical gas to the premises where the filling takes place, or directly to tanks located in other establishments, shall be carried out under the technical responsibility of the Technical Director of the manufacturer.

2 – The functions of Technical Director of the manufacturer are assumed by a pharmacist specialising in the pharmaceutical industry, registered with the Order of Pharmacists and subject to the duties resulting from Decree-Law No 288/2001 of 10 November 2001, as amended.

3 – The Technical Director of the manufacturer shall be responsible for:

a) Checking the operations connected with the filling of the medical gas;

b) The supervision of operations carried out at the places assigned to the manufacturer, in particular the release of batches at the plant producing the active substance and the monitoring of transport and transfer operations into the tanks of its customers;

c) Identification of stored medical gases;

d) By the type of existing fixed tanks and their quantity.

4 – The Technical Director of the manufacturer may not cumulate technical management functions in more than five manufacturing sites held by the same legal entity.

5 – The Technical Director's sresponsibilities must be fulfilled personally and may delegate tasks, but not responsibilities specific to the position of technical management.

6 – The manufacturing authorisation holder shall ensure that the Technical Director is permanently reachable.

7 – Personnel involved in the production, storage and supply of medical gas shall be appropriately qualified in Good Manufacturing Practices and Good Distribution Practices for medicinal products, depending on the duties specifically performed by them.

Article 11
Manufacturing process

1 – In order to ensure the quality and traceability of medical gases, fixed tanks installed on the manufacturer’s premises and filling sites shall be dedicated to a single type of medical gas with defined quality specifications.

2 – In the manufacturer's units authorised to fill gas cylinders, assemblies of cylinders or mobile cryogenic tanks, medical gas may be stored in dedicated fixed cryogenic tanks, which supply the filling systems, or be produced by means of production equipment, in particular medical compressed air compressors.

3 – The same reservoir installed in the production plant may supply different fixed reservoirs placed at manufacturing sites, hospitals, public or private health services with pharmaceutical services or wholesale distributors.

4 – The use of tanks for non-medicinal purposes is only permitted if the Technical Director demonstrates that there is no risk of contamination in accordance with Good Manufacturing Practices.

5 – The filling of cylinders shall be allowed only to the manufacturers of medical gases and in places duly authorised for the manufacture of medical gases.

6 – The interruption or suspension of manufacturing operations at the manufacturer's premises does not necessarily entail the expiry of the manufacturing authorisation for that site, which may be maintained for batch release operations at the premises for the manufacture of the active substance, for the monitoring of transport operations and for the transfer to premises assigned to the manufacturer, in particular in hospitals, public or private health services with pharmaceutical services, and entities meeting the requirements laid down in this Regulation, provided that it continues to have technical management.

7 – The manufacturing process shall in particular comply with Annex 6 of the 'Guide to Good Manufacturing Practice' published by the European Commission in Volume 4 of the rules governing medicinal products in the European Union.

Section I

Manufacture of medical gases in health institutions using medical devices

Article 12

Definition

1 – The manufacture of medical gases in health institutions, through the use of medical devices, for clinical use, includes all processes to obtain a product in accordance with the respective specifications in force.

2 – The manufacture of these medical gases comprises all kinds of activities from production to clinical use in health institutions.

Article 13
Applicable legal framework

1 – This Chapter shall apply to public legal persons, military institutions, private social solidarity institutions and private entities that manufacture medical gases, as defined in Article 3 (aa) of Decree-Law No 176/2006 of 30 August 2006, for clinical use on their own premises, from the use of medical devices.

2 – The manufacturing activities referred to in the previous article shall be subject to the provisions of Decree-Law No 176/2006 of 30 August 2006, Decree-Law No 95/2004 of 22 April 2004, Order No 594/2004 of 2 June 2004, the rules set out in this chapter, and shall take into account the directives, guidelines or interpretations issued by the competent bodies of the European Community.

3 – The medical devices used in the manufacturing activities must comply with the provisions of the legislation applicable to them.

Article 14
Notification

The manufacture of medical gases in public legal persons, military institutions, private social solidarity institutions and private entities, through the use of medical devices, for clinical use, is subject to prior notification to INFARMED, I.P., to be submitted on the website of this Institute.

Article 15
Quality Management System

1 – The health establishment or service, public, private, corporate or social, shall define, implement and maintain a quality management

system that establishes responsibilities, procedures and principles of risk management in relation to its activities.

2 – A pharmacist responsible for the implementation of the quality management system as well as for ensuring compliance with the specifications of the medical gases manufactured and used shall be designated.

3 – The quality management system must be properly supported by appropriate documentation, such as procedures, work instructions or records, that covers all activities carried out in the manufacture of medical gases, through the use of medical devices, for clinical use on the premises of such health establishments or services and which allows them to be tracked.

4 – The documentation referred to in the preceding paragraph shall:

a) Be legible, clear, unambiguous, up-to-date and duly approved;
b) The documentation consists of all written procedures, instructions, agreements, records and data, in paper or electronic form.
c) Be kept and maintained for a period of 5 years, as well as be readily available and accessible.

5 – As part of the quality management system provided for in the preceding paragraphs, it shall be established and demonstrated that the medical gas produced complies with the requirements of the approved monograph of the European Pharmacopoeia or of a pharmacopoeia of another Member State of the European Union.

Article 16
Staff

1 – There must be competent staff who ensure the proper performance of all medical gas manufacturing activities at health institutions using medical devices.

2 – All staff should have a description of roles and responsibilities as well as replacement schemes. The hierarchical and functional relationship of employees should be reflected through an organisation chart.

3 – Staff shall be provided with regular training and qualification appropriate to the duties to be performed and ensuring that their technical and scientific updating is maintained.

4 – The manufacture of medical gases, for clinical use in its own facilities, from the use of medical devices, in health institutions, health services, public, private, corporate or social, is the responsibility of the pharmacist Technical Director.

Article 17

Fixtures and fittings

1 – Adequate and sufficient facilities and equipment must be in place to ensure that medical gas manufacturing activities are properly carried out in health institutions using medical devices in accordance with the approved specifications.

2 – Facilities shall be designed and maintained using materials that are fit for purpose and an adequate level of cleaning shall be ensured and measures shall be implemented to prevent the presence of pests in these facilities.

3 – Facilities shall have arrangements in place to ensure that only authorised persons have access to them.

4 – The entire circuit associated with these gases shall ensure that they are not susceptible to cross-contamination and do not contaminate other products, including products with different concentrations.

5 – All equipment used for these activities shall be installed and maintained in such a way as to ensure its proper functioning, in accordance with the applicable technical standards, ensuring that

this equipment is checked, calibrated and/or maintained, as applicable.

6 – The instructions for use of the manufacturers of medical devices used in the manufacturing activities of these medical gases shall be followed.

7 – The obligations relating to the reporting of serious incidents with medical devices used in accordance with the provisions of the legislation in force shall apply.

8 – Where computer systems are used, their suitability shall be demonstrated and their validation and/or verification shall be carried out, ensuring that only authorised persons can access, verify and modify data and ensure its legibility and integrity.

Article 18

Quality control

1 – The establishment or health service, public, private, corporate or social, that manufactures and uses in its own facilities these medical gases is responsible for the definition and implementation of the laboratory tests to be carried out, with a view to the effective quality control of the equipment used and the medical gases.

2 – The quality control provided for in the previous paragraph shall be carried out at appropriate intervals ensuring the quality of the latter in accordance with the specifications in force.

3 – The quality control of the medical gas provided for in the preceding paragraphs shall demonstrate compliance with the requirements of the approved monograph of the European Pharmacopoeia or of a pharmacopoeia of another Member State of the European Union.

Chapter III

Transport

Article 19
Transport Conditions

1 – The transport conditions of the medical gases must comply with the rules in force, in particular the applicable national and/or international rules on the transport of dangerous goods.

2 – The specific transport conditions of the medical gas are described in the summary of product characteristics contained in the marketing authorisation dossier.

3 – The medical gas contained in the tank shall not be delivered and transferred to the fixed tanks of the entities legally entitled to acquire medical gases without the batch release having previously taken place.

Article 20
Bulk transport and supply

1 – The transport and supply of medical gas to the structures assigned to the entities is carried out directly from a tank which was filled from the fixed reservoir located in the medical gas production plant.

2 – The same tank may be supplied to different installations.

3 – The quality of the medical gases must be guaranteed in the supply of the fixed tanks and must be carried out by one of the following processes:

a) Analytical control of the medical gas contained in the tank before filling the user’s tanks or;

b) Analytical control of medical gas that is contained in the fixed tanks after filling.

4 – Fixed cryogenic tanks located on the premises of entities that are replenished by tanks dedicated to a type of medical gas do not

need to be sampled after fuelling, provided that a certificate of analysis of the contents of the tank is provided.

5 – Cryogenic tanks located on the premises of the entities shall be monitored and controlled at a frequency that allows quality parameters to be safeguarded.

6 – Tanks located on the entities' premises must be filled by the manufacturer's suitably qualified staff and under the responsibility of the Technical Director.

7 – The manufacturer and, in the absence of a national manufacturer authorised in accordance with Article 7(1), the marketing authorisation holder shall be responsible for the quality, safety and efficacy of the medical gas up to the outlet valve of the fixed cryogenic reservoirs located in hospitals, public or private health services with pharmaceutical services or wholesale distributors.

8 – In the case of supply of medical gases from other Member States, the manufacturer, the marketing authorisation holder and the customer located in the national territory shall comply with the provisions set out in the previous paragraphs and shall be able to demonstrate that the fed fixed tank has been the subject of all necessary measures to prevent its contamination, in particular effective maintenance, installation of a control system dedicated to medical gas or performance of increased controls in the case of supply by another supplier.

9 – In the situations referred to in paragraphs 7 and 8 of this Article, where the manufacturer and the marketing authorisation holder are different legal entities, a written agreement clearly defining the responsibilities of each party shall be established.

Article 21

Transport of cylinders

1 – The cylinders shall be transported with appropriate material in order to protect them from the risk of shocks and falls in a stable manner.

2 – The transport of cylinders must comply with the provisions of the legislation in force on the transport of dangerous goods.

3 – Full gas cylinders and mobile cryogenic tanks shall be transported covered, protected from adverse weather conditions, so that they are delivered in a clean and sound condition compatible with the environment in which they are to be used.

4 – The requirements described in the preceding paragraph shall also be applied to the set of cylinders, except for transport in a covered manner.

Chapter IV
Distribution

Article 22
Wholesale Distribution

1 – The activity of wholesale distribution of medical gases complies with the provisions of the Law, the Good Distribution of Medicinal Products and this Regulation.

2 – Medicinal gases packaged in cylinders may only be stored and distributed by wholesale distributors of medicinal products who have a specific authorisation from INFARMED, I.P., for wholesale distribution of medical gases.

3 – Under no circumstances may the wholesale distributor carry out filling operations.

4 – The facilities used shall comply with the Good Distribution Practice for Medicinal Products and the requirements set out in the following article.

5 – The distributor shall have premises reserved exclusively for the storage of medical gases, segregated from the other premises, and no other products may be stored there.

Article 23

Storage conditions

1 – Storage sites must comply with the following conditions:

a) Indoor space: well-ventilated and damp protected installations;
b) Outdoor space: in ventilated places, protected from rain, direct sunlight and humidity;
c) Anti-shock and anti-fall conditions;
d) Absence of oxidising, flammable materials, heat or ignition sources.

2 – Compliance with legislation and other rules relating to the storage and handling of pressure tanks shall be observed, without prejudice to the observation of the requirements for keeping the cylinders upright or sloping if justified.

Article 24

Licensing and technical direction

1 – Interested parties must apply to INFARMED, I.P. for authorisation of wholesale distribution of medicinal products for human use, in accordance with the provisions of Articles 94 et seq. of Decree-Law No 176/2006 of 30 August 2006, as amended.

2 – Without prejudice to the application of the elements provided for in Article 96(1) and (2) of Decree-Law No 176/2006 of 30 August 2006, the application for authorisation provided for in the preceding paragraph must contain the indication that it refers to the pursuit of the activity of wholesale distribution of medical gases.

3 – The activity of wholesale distribution of medical gases shall be permitted only where the person concerned has an adequate number of technical managers to ensure that each person is responsible for a

number of storage sites equal to or less than five, even if located in separate premises.

4 – The Technical Director shall perform his duties personally and may delegate tasks, but not responsibilities specific to the position of technical management.

5 – The holder of the authorisation for the wholesale distribution of medical gases shall ensure that:

a) The Technical Director is permanently contactable;
b) At all times, the storage facilities shall have competent staff with proven knowledge of all stages of distribution activities;
c) The number of competent staff members is appropriate to the volume and scope of the activities of wholesale distribution of medical gases carried out;
d) The professional qualification of the staff referred to in b) and c) shall be the responsibility of the Technical Director;
e) The roles and tasks of the staff involved shall be defined in writing, including through the description of their functions and the replacement mechanisms.

Chapter V
Acquisition, supply, dispensation and home delivery

Article 25
Direct acquisition

Public and private entities providing support in medical emergency situations, as well as entities involved in land, sea or air rescue situations, may, by means of a direct acquisition authorisation granted by INFARMED, I.P., acquire medical gases for their own use, pursuant to Article 79 of Decree-Law No 176/2006 of 30 August 2006.

Article 26

Dispensing to the public

The activities of dispensing or supplying medical gases to the public may only be pursued by entities that fulfil the requirements laid down in this Regulation.

Article 27

Home distribution

1 – The home distribution of medical gases is subject to prior authorisation by INFARMED, I.P.

2 – Without prejudice to the provisions of the preceding paragraph, the home distribution of medical gases shall not be subject to prior authorisation by INFARMED, I.P. where it is carried out by:

a) Entity which holds an authorisation for wholesale distribution or for the manufacture of medicinal products for human use, granted under Decree-Law No 176/2006 of 30 August 2006, in its current form;

b) Entity forming part of a group of related companies, to which already belongs a company holding an authorisation for the wholesale distribution of medicinal products for human use, granted under Decree-Law No 176/2006 of 30 August 2006.

3 – The provisions of the preceding paragraph shall not exempt the holder from compliance with the other provisions of this Regulation and the Good Home Distribution Practices for Medicinal Products listed in Annex I thereto, which forms an integral part thereof.

4 – Workshop pharmacies do not require authorisation for the exercise of home distribution of medical gases, but are subject to compliance with the provisions of this Regulation and the Good Practices for Home Distribution of Medical Gases.

4 – Entities authorised to carry out home distribution and delivery may not under any circumstances carry out filling operations.

Article 28

Start-of-Activity Communication

1 – Entities wishing to carry out the activity of home distribution of medical gases shall communicate the start of activity to INFARMED, I.P. by indicating the following information:

a) Name or company and domicile or head office;
b) Identification number of the legal entity assigned by the National Register of Legal Entities or tax identification number;
c) Identification of the Technical Director.

2 – In the case of the entities referred to in Article 27(1)(b), the related company that has authorisation for the wholesale distribution of medicinal products for human use, issued under Decree-Law No 176/2006 of 30 August 2006, must also be indicated.

3 – Prior notification of any change to the registered data is mandatory, and the register must be kept up to date at all times.

4 – INFARMED, I.P., shall make available on its website the list of entities that have communicated the exercise of the home distribution of medical gases.

Article 29.

Obligations of the home distributor of medical gases

1 – Home distributors of medical gases shall be obliged to:

a) Register in advance with the ERS in the context of the provision of home respiratory care;
b) Have technical management and staff with adequate qualifications and training;
c) Have a quality assurance system, including a manual of procedures describing the general organisation, in particular

as regards distribution and delivery activity, dispensation, traceability, batch recalls, pharmacovigilance and the surveillance of medical devices;

d) Ensure that the medical gases they purchase are stored in facilities that comply with good manufacturing or distribution practices.
e) Deliver the equipment to the patient's home and provide him with the corresponding technical information, as well as the rules of safety, proper functioning and hygiene rules related to its use;
f) Take back equipment, where appropriate;
g) Ensure that home respiratory care providers, the patient and those around them are adequately informed about the rules for the use, hygiene and cleaning of equipment and other materials;
h) Ensure the technical maintenance of the equipment, in compliance with the requirements of the manufacturer, as well as the surveillance of the equipment installed in the patient's home;
i) Have a telephone answering service that operates 24 hours a day every day of the year;
j) Develop and implement a distribution and delivery procedure that avoids disruption of supply, either in cases of short or long-term treatment;
k) Repair or replace defective equipment without prejudice or damage to the patient;
l) Ensure appropriate transport conditions in accordance with this Regulation;
m) In the case of subcontracting, ensure that the subcontractor complies with the legal and regulatory provisions in force.

2 – To communicate to INFARMED, I.P., under the terms and at the intervals to be defined by it, the quantities of medical gases distributed.

3 – Home distributors must have means of communication by electronic means that allow the expeditious receipt of safety and quality alerts sent by INFARMED, I.P.

4 – Home distributors must provide INFARMED, I.P. with all information and access to premises and installations within the scope of their supervisory powers.

5 – Without prejudice to the provisions of paragraph 1 of the preceding Article, the activity of home distribution of medical gases is conditional upon compliance with the provisions of the preceding paragraphs, under penalty of INFARMED, I.P. being able to suspend or cease the exercise of the activity of home distribution of medical gases.

Chapter VI
Management of medical gases for clinical use in a health facility or service

Article 30
Scope

1 – This Chapter shall apply to the entire circuit of medical gases for clinical use in an establishment or health service purchased from entities legally authorised to supply them.

2 – The circuit of these gases includes all kinds of activities from their acquisition to their use.

Article 31
Quality Management System

The provisions of Article 15 shall apply, with the necessary adjustments, to the management of medical gases for clinical use in a health establishment or service.

Article 32
Staff

1 – There must be competent staff who ensure the appropriate performance of all activities covered by the medical gas management circuit for clinical use in a health establishment or service.

2 – All staff should have a description of roles and responsibilities, as well as replacement schemes, and the hierarchical and functional relationship between staff members should be reflected in an organisational chart.

3 – Staff shall be provided with regular training and qualification appropriate to the duties to be performed and ensuring that their technical and scientific updating is maintained.

Article 33
Fixtures and fittings

1 – There must be appropriate and sufficient premises and equipment in order to ensure proper performance of the activities for the management of medical gases for clinical use in a health establishment or service, enabling proper receipt, storage and dispensing of the gases.

2 – Facilities shall be designed and maintained using materials that are fit for purpose, and an adequate level of maintenance, cleaning and measures to prevent the presence of weeds in the facilities shall be ensured.

3 – Facilities shall have arrangements in place to ensure that only authorised persons have access to them.

4 – The entire circuit associated with these gases must ensure that they are not susceptible to contamination or contaminate other products, including products with different concentrations.

5 – In order to allow the traceability of the gases referred to in the preceding paragraph, the existence of segregated circuits and equipment must be guaranteed, and compliance with the applicable standards, in particular ISO 7396 and ISO 10083.

6 – All equipment used in connection with these activities must:

a) Be designed, installed and maintained in such a way as to ensure their proper functioning;
b) Be verified, calibrated and/or maintained as applicable and comply with the other legal requirements;
c) The instructions of the manufacturers of the respective equipment must be observed.

7 – Where computer systems are used, their suitability shall be demonstrated and their validation and/or verification shall be carried out, ensuring that only authorised persons can access, verify and modify data and ensure its legibility and integrity.

Article 34

Monitoring of distributionsystems

The health establishment or service shall be responsible for ensuring that the distribution systems for these gases are properly maintained and monitored, ensuring that appropriate tests are carried out at appropriate intervals, taking account also of the instructions of the respective manufacturers.

Chapter VII

Prescription and information for users

Article 35

Medical prescription

Medical gas is dispensed or administered to the user in accordance with a medical prescription.

Article 36

Information to the public

All the necessary information regarding the technical specificities of treatment with medical gases must be duly communicated by the health professionals of the entity to the respective users, or to their household or their legal representative in case of impediment or disability, under the terms provided for in the Good Practices of Home Distribution of Medical Gases.

Chapter VIII

Final provisions

Article 37

Final provisions

1 – Without prejudice to the provisions of this Regulation and other applicable legislation, the following acts shall also apply, with the necessary adjustments to entities carrying out the activities referred to in Article 1:

a) Regulation on the Management of Availability of Medicinal Products;
b) Regulations for the Installation and Operation of Simple Pressure Vessels and Pressure Equipment;
c) General regime for the legal metrological control of measuring methods and instruments and respective regulations.

2 – The entities covered by this Regulation must also comply with the requirements set out in standards/technical specifications, issued or to be issued in particular by the Central Administration of the Health System, I.P., or by another entity that succeeds it in its respective duties.

Annex I

(Referred to in Article 22(2) of the Medical Gases Regulation)

GOOD HOUSEHOLD DISTRIBUTION PRACTICES (BPDD) FOR MEDICINAL GASES

INTRODUCTION

The Good Practices of Home Distribution of Medical Gases are applicable to entities and pharmacies that, under the responsibility of a pharmacist, carry out the activity of home distribution of medical gases.

It covers all operations for the home distribution of medical gases, including operations carried out at the patient's home for the administration of medical gases, the handling of tanks and associated medical devices, the preparation of cryogenic reservoirs and the provision of information necessary for home respiratory care providers and the patient for the proper use of medical gases, and are therefore applicable to industrially manufactured medical gases with a marketing authorisation.

Good practices are without prejudice to the application of other standards to which the activities of home distribution of medical gases are subject.

Chapter I

QUALITY ASSURANCE SYSTEM

1.1. Principles

The quality assurance system is a system of good practice according to standards aimed at the objective of verifying and monitoring the quality of home distribution of medical gases.

It represents the set of measures implemented to ensure that medical gases are distributed to the home in accordance with the necessary requirements.

Home distributors shall maintain a quality assurance system that establishes responsibilities, procedures and risk management principles in relation to their activities.

All distribution activities should be clearly defined and systematically verified. All critical steps in the distribution processes and significant changes shall be justified and, where appropriate, validated.

A quality assurance system suitable for the home distribution of medical gases must be able to ensure that:

1.1.1. The medical gas delivered to the home has been manufactured by an authorised manufacturer which complies with the good manufacturing practices inherent in this type of production;

1.1.2. The distribution operations, for the purpose of home distribution of medical gases, are clearly described in line with the good practices applicable to these operations;

1.1.3. There is an organisational chart which identifies and designates the responsible persons;

1.1.4. The technical and organisational arrangements are adopted and implemented in such a way that the supply of the medical gases, as well as the reservoirs and devices involved in their home distribution are those indicated for that purpose, in particular as regards the regularity of supply to patients and the quality of the medical gases dispensed;

1.1.5. All necessary controls, as well as qualifications and validations, on medical gases, as well as on reservoirs and devices involved in their home distribution, are carried out in accordance with the rules and procedures in force;

1.1.6. The documentary system is satisfactory and adequate;

1.1.7. The batch management system for medical gases, as well as that of the tanks and devices involved in their home distribution, allows their traceability and their possible collection under the best conditions;

1.1.8. There is a self-inspection and/or quality audit procedure that regularly assesses the effectiveness and implementation of this quality assurance system;

1.1.9. The response to emergency situations is ensured correctly, in accordance with a pre-established procedure.

1.2. Self-inspection

Self-inspections are part of the quality assurance system and should be carried out on a regular basis in accordance with a pre-established programme to ensure enforcement and compliance with good practice.

1.2.1. Self-inspections shall be conducted independently, in accordance with a written procedure, by persons appropriately qualified and appointed for that purpose.

The purpose of these is to verify:

- The compliance of the rooms and the material;

- The compliance and updating of documents;

- The compliance of staff's training level;

- Compliance with the procedures;

- The implementation and respect of best practices;

They are the subject of a written, dated and signed minutes.

1.2.2. The minutes shall contain the observations made during the self-inspection and, where appropriate, the proposals for corrective action. The follow-up of corrective actions should be effective and formalised.

1.3. Management of outsourced activities

1.3.1. The quality system shall cover the control and verification of all subcontracted activities related to the supply, possession, supply and home distribution of medical gases.

1.3.2. These processes should incorporate quality risk management and include:

a) The assessment of the suitability and competence of the contractor to perform the activity and verify the status of the authorisation, if necessary;

b) The definition of the responsibilities and communication processes of the parties involved in relation to quality-related activities;

c) The monitoring and verification of the performance of the contractor, as well as the regular identification and implementation of any necessary improvements.

1.4. Risk management

1.4.1. Quality risk management is a systematic process of assessment, control, communication and verification of risks to the quality of medical gases. It can be applied both proactively and retrospectively.

1.4.2. Quality risk management should ensure that the assessment of quality risks is based on scientific knowledge, experience with the process and, finally, taking into account patient protection. The level of effort, formality and documentation of the process should be proportionate to the level of risk.

Chapter II

STAFFS

2.1. Responsibility of the Technical Director

All the operations performed by the entities in the development of the activity of home distribution of medical gases are under the responsibility of the pharmacist Technical Director.

2.1.1. The Technical Director is in charge of home distribution and is responsible for all the organisation's activities, at all stages of the operations it carries out, from its own supply to home distribution of medical gases.

The responsibilities of the Technical Director include, inter alia:

a) Drawing up procedures for advising the respiratory home care provider, patient and/or those around him/her, and in particular for disseminating safety instructions;

b) Monitoring and coordinating, home respiratory care providers, the treatment of the patient;

c) Ensuring the pharmacovigilance system and surveillance of medical devices used;

d) Ensure traceability of batches, complaints and recalls;

e) Observe and enforce the safety rules;

f) Respect and enforce Good Practices for Home Distribution of Medical Gases;

g) Be responsible for the operation of medical devices, insofar as they contribute to the administration of medical gases to the patient;

h) Ensure that the quality management system is implemented and maintained;

i) Ensure the training of staff and the quality of the service provided by them;

j) Coordinate the entire activity.

2.1.2. The pharmacist Technical Director shall be independent, technically and ethically in the performance of his duties.

The Technical Director shall be designated by the heads of the entity, who shall ensure independence in order to enable full assumption of responsibilities, by providing the necessary means and staff in sufficient numbers and of adequate quality.

In the absence of agreement on standards established in the interest of public health, in situations where the Technical Director opposes a management, administrative or management body of an entity that distributes medical gases at home, the pharmacist Technical Director responsible for the distribution of medical gases must inform INFARMED, I.P. and the Order of Pharmacists of this situation.

2.1.3. The pharmacist Technical Director is responsible for the implementation and enforcement of best practices.

Any violation of the Good Practices of Home Distribution of Medical Gases should be reported to you.

2.1.4. The home distribution of medical gases is carried out by the staff of the entity duly authorised for this purpose, in accordance with the instructions given by the Technical Director on the basis of the established procedures.

2.1.5.

The pharmacist Technical Director shall ensure that the installation of equipment and any associated medical devices has been properly carried out and that the information provided to the provider of home respiratory care, patient and household will enable them to achieve a good level of understanding of the operation and handling of equipment and treatment constraints, with the aim of promoting adherence to therapy and rational use of the medicinal product.

2.1.6. In the course of the treatment of patients, the Technical Director shall intervene at home if necessary and may request all relevant information from the prescribing doctor in order to ensure that the treatment is carried out properly.

2.1.7. The Technical Director shall complete the pharmacovigilance notification sheets and ensure compliance with the authority's obligations relating to the surveillance of medical devices associated with the home distribution of medical gases.

Any incident or serious reaction or adverse reaction found at the time of home distribution shall be immediately pointed out. All precautions and measures must be taken in the interests of the patient, in conjunction, if necessary, with the prescribing doctor.

2.1.8. The pharmacist Technical Director responsible for home distribution performs his duties effectively and continuously, with regard to the performance of his technical and administrative duties.

The Technical Director may delegate tasks but not responsibilities.

The competent staff involved in all phases of the home distribution activities shall be qualified by the Technical Director. The number of herds needed depends on the volume and scope of home distribution activities.

The tasks described in paragraph 2.1.4 presuppose the existence of a greater number of pharmacists than that laid down in this paragraph, assisting the Technical Director in the

performance of his duties which must be provided for, and with the responsibilities defined, in the manual of procedures.

2.2. Protection of Staff

Staff shall have appropriate qualifications and qualifications for the performance of their duties.

2.2.1. Qualifications

Staff shall have qualifications and qualifications appropriate to the performance of duties associated with the home distribution of medical gases and theoretical and practical training shall be provided with a view to updating knowledge.

This qualification is nominative and is acquired following training. Experience in the function may also be taken into account when assessing qualifications appropriate to the performance of the duties.

2.2.2. Training

Appropriate theoretical and practical training, with regard to home distribution of medical gases and good practices, should be ensured for newly recruited staff and staff taking up a new role, as well as for staff in post at the date of entry into force of the good practices. Its content is validated by the pharmacist Technical Director.

The theoretical training shall cover operations carried out at the patient’s home with medical equipment, medical devices and medical gases, the physical and chemical characteristics of medical gases, the regulatory framework for medicinal products and the risks inherent in the use of medical gases.

The practical training shall enable staff to carry out their duties properly and shall address:

- Security precautions

- Description, operation, maintenance, installation at the patient's home of reservoirs and medical devices necessary for the administration of medical gases;

- Communication, information and clarification of the patient.

The trainings are adapted to the category of staff concerned. Staff benefit from continuous professional training that allows them to update their knowledge.

2.2.3. Annual training plan

The training plan for qualified staff must be approved by the pharmacist responsible for the home distribution of medical gases.

2.2.4. Hygiene

Detailed hygiene information and/or training programmes should be established, implemented in a manner appropriate to the different needs of the home distribution company. They shall include procedures relating to the physical conditions of health, hygiene and clothing of staff.

Chapter III

OPERATIONS

The treatment of patients with medical gases can lead to significant risks to human safety. The safety rules must be in accordance with this Regulation and other legal rules in force and must be complied with.

Home distributors engaged in the activity of medical gases shall implement appropriate safety measures, in accordance with the rules in force and current practices, with regard to the supply, maintenance, storage, handling and transport of medical gases in order to avoid deterioration and contamination of the medical gas, as well as the risk of error by replacing the medical gases to be administered to the patient.

3.1. Refuelling

3.1.1. Supplies may be made only from manufacturers and entities authorised for the wholesale distribution of medicinal products in accordance with the provisions of the legislation in force.

3.1.2. Products shall be examined at reception to ensure that containers are not damaged and that products maintain their integrity. It should be checked that the products are properly identified, with regard to the labelling of the medical gas, batch number, date of manufacture and the respective expiry dates, as well as the quantity delivered.

3.2 Cleaning

Before the home distribution to the patient, it should be verified that the reservoirs have been cleaned and all parts of the medical devices necessary for the administration of the medical gases that are not in direct contact with the patient have been disinfected.

3.3. Fractionation

3.3.1. No operation may be carried out by the residential distribution house of medical gases for the filling of the mobile cryogenic cylinders and tanks until their delivery to the patient. For this purpose, the valve outlets shall retain their tamper-proofing system.

Only manufacturers may perform the filling of cylinders and home cryogenic tanks.

The manufacturer may carry out fractionation and filling operations of home cryogenic cylinders and reservoirs in order and on behalf of entities, namely pharmacies, and entities engaged in the activity of home distribution and must ensure that the home cryogenic cylinders and reservoirs comply with the approved specifications.

3.3.2. No quality control of the medical gas can be performed, in addition to those already carried out by the manufacturer, in the cylinders the system of guarantee of inviolability of the valves is maintained, until the distribution in the patients' homes.

3.4. Maintenance

3.4.1. Defective materials must be identified and stored separately.

3.4.2. The maintenance of the medical devices necessary for the home distribution of medical gases must be carried out in accordance with the manufacturer’s recommendations.

No maintenance or repair operation may be carried out by the home medical gas distributor on the cryogenic cylinders and tanks.

In particular, it is formally forbidden to lubricate valves, connections, flow control valves, and other medical devices in contact with medical gas.

The flow control valve, for the specific risks it generates, shall be maintained or repaired by the manufacturer or by a sub-contracted entity approved by the manufacturer.

The only operations authorised relate to their normal use, namely the change of connection joint over the cylinder and the verification of rates and pressures and are carried out without the use of tools.

Only a gasket compatible with the medical gas must be used.

3.4.3. After any maintenance operation necessarily involving exposure to the open air of the inner tank and its circuits, the cryogenic tanks shall be returned to the manufacturer for the necessary checks.

3.5. Storage

3.5.1. Cylinders and home cryogenic tanks shall be stored in a clean, ventilated or ventilated place reserved for the storage of medical gas with restricted access.

They shall be protected from the risk of shocks and falls, from sources of heat or ignition, from temperatures above 50 °C, from combustible materials and from bad weather.

Access to these storages shall be restricted to authorised staff

3.5.2. In the home distribution entities, the storage areas of the cylinders must allow the separation of the different gases and the full and empty cylinders, as well as the rotation of stocks.

3.5.3. A separate area must be allocated to the storage of medical gases that are the subject of a complaint, and which are subject to collection or return.

3.5.4. A separate area shall be allocated to the storage of defective home cryogenic cylinders and containers.

3.5.5 There must be a pharmacist responsible for the storage activities associated with home distribution, who assists the Technical Director of home distribution.

Where a storage site is located in the same building or condominium where other facilities included in an authorisation for the wholesale distribution of medical gases already exist, the Technical Director attached to those facilities may combine those functions with those of the person responsible for the storage of the home distribution.

3.6. Transport - vehicles

3.6.1. Medicinal gas is transported in a vehicle that safeguards staffsafety and allows the quality of the products to be maintained. The transport vehicle shall meet at least the following conditions:

- Covered and protecting the cylinders, home reservoirs and medical devices from the weather;

- Has a partition which separates the driver’s cabin from the transport compartment where the cryogenic tanks are transported;

- Has adequate ventilation conditions in the compartment where the home cryogenic cylinders and tanks are transported;

- Not to transport flammable substances in the transport compartment;

- Affixing the inscription “smoking prohibited”;

- The existence of means for emergency situations, in particular the existence of at least one fire extinguisher;

- Systems for fixing medical gas cylinders and cryogenic tanks.

3.6.2. Exceptionally, rule 3.6.1 may be waived for a delivery that is made in an emergency to a maximum of one patient and in accordance with the recommendations of the manufacturers. To this end, the cylinders and/or tanks shall be installed on the vehicle exactly before its departure and removed after its return.

3.6.3. Gas cylinders and home cryogenic tanks shall be securely packed. Cylinders with a capacity exceeding 10 litres of water or liquefied gas must be transported in a vertical position.

3.6.4. Before any overhaul or repair of the vehicle, the Home Distribution Authority shall remove the cylinders and cryogenic containers from the vehicle and inform those involved of the precautions to be taken depending on the nature of the material transported.

Chapter IV

DOCUMENTATION

4.1. Quality assurance system documentation

Documentation is an essential element of the quality assurance system. It includes, on the one hand, written procedures that must be followed and, on the other hand, documents that make it possible to follow the performance of all the operations involved in the home distribution of medical gases, certifying that all the operations have been carried out in accordance with the aforementioned procedures.

4.1.1. The operations in question are as follows:

- Training;

- Staff qualifications and skills

- Reception;

- Identification of medical gases;

- Device calibration

- Equipment management

- Verification of associated medical devices;

- Transport to the patient's home;

- Home visit;

- Installation of the equipment in the patient’s home;

- Complaints;

- Collections;

- Self-inspection;

- Pharmacovigilance and the surveillance of medical devices.

4.1.2. Distribution operations for the purpose of home distribution are clearly described in written procedures.

4.1.3. Documents describing the procedures should be carefully prepared, drafted and regularly updated. They must be validated, signed and dated by the pharmacist Technical Director responsible for home delivery before they are handed over to the staff.

4.1.4. The entity engaged in the activity of home distribution must have models of pre-prepared documents relating to all the operations and specific documents relating to the home distribution of each lot, which must make it possible to reconstruct the history of each lot dispensed. All documents must be kept for at least five years after the end of the batch dispensation.

4.1.5. Document templates should not be handwritten. Any correction must be dated and signed. The documents reproduced must be clear and legible. The system for reproducing working documents from the originals should ensure that no errors are introduced.

4.1.6. The document templates should be regularly reviewed and updated. Inadvertent use of obsolete documents should not be possible.

4.1.7. A batch distribution process shall be established for each batch, allowing for its traceability. It shall contain the batch number of the medical gas subject to home distribution, as well as the name and address of each recipient patient.

4.1.8. For each cryogenic tank, the documentary system shall allow traceability on a chronological basis of:

- Inspection or repair operations;

- The batch numbers of the medical gas contained in that cryogenic reservoir;

- The names of the patients;

- The place where it is located.

4.1.9. Measuring instruments: Measuring instruments are calibrated and checked at defined intervals and by appropriate methods. The minutes of the checks shall be kept for five years.

Chapter V

HOME

When installing medical gases in the patient's home, it is important to check that all the conditions are in place for the treatment to take place normally, especially with regard to safety conditions for the patient and the surrounding environment.

5.1. Installation preparation

5.1.1. The set of medical devices necessary for the application of the medical gases is provided in accordance with the prescription. However, if in doubt about the prescription, these devices can be supplied in accordance with instructions provided by the Technical Director and authorised staff.

5.1.2. For prolonged treatments, if necessary, a source of medical gas may be made available to the patient for emergency or outpatient situations.

5.2. Installation at home

5.2.1. A check is carried out to ensure that the patient's environment meets the safety conditions relating to the tank and the use of medical gases. At least the following points shall be taken into account at the time of this check:

- Sources of heat, naked flames, ignition points (chimney, stove, radiator, heater);

- Deposit of flammable material (paper, wood, solvent);

- Passage area (corridor);

- Volume or ventilation of places of deposit and use

- Absence of solvents (alcohol, petrol) in these places;

- Presence of porous and flammable soil as carpet

- Accessibility of the dwelling to enable delivery in good condition;

- Ability of the patient or his/her household to handle the reservoir and/or equipment.

5.2.2. As some of the medical gases are an oxidising gas, smoking by the patient or by someone in their household must be given special attention.

5.2.3. Taking into account the prior verification and the administration of the medical gas to the patient, the place of deposit and use of the medical gas shall be determined.

5.2.4. The staff shall assemble, adapt as necessary and adjust the entire medical gas source in order to ensure proper functioning, taking into account suitability for the patient. It carries out the demonstrations, as well as providing information on the necessary technical specificities of the treatment, as provided for in point 5.3., in order to ensure the correct use by the patient.

5.2.5. The residential distribution entity for medical gases shall provide the patient with the consumable elements, in particular the pipes carrying the medical gases.

5.2.6. The discovery of any element of risk or improper use is reported to the pharmacist, who assesses the need to inform the prescribing doctor. The pharmacist ensures the conformity of the installation carried out and the information provided.

5.3. Public information

5.3.1. The home medical gas distribution organisation ensures that the home respiratory care provider is provided with the necessary information regarding the technical specificities of the treatment.

The information includes, in general, the safety instructions and the methods of use of the medical gases, as well as the practical handling of the material, in particular:

a) The duration of treatment, the use (number of hours per day), the conditions of use (at night, during the day, under ventilation, at rest, in effort) of the dose or the rate of use (number of litre/minute);

b) The safety instructions relating to the use of this medicinal product;

c) TT medicinal product must not be stored or used at a distance of less than two metres from a flame or heat source;

d) Smoking or authorising smoking is not permitted in a place where the medicine is used or stored;

e) The medicinal product should not be stored or used in the vicinity of any spark-producing appliance;

f) The medicine should not be stored in a poorly aerated or poorly ventilated place.

g) A Using pressurised aerosol dispensers (deodorant, lacquer, insecticide) or solvent (alcohol, petrol) is prohibited in that location.

It also includes advice to facilitate the integration of the material into patients' lives.

5.3.2. The competent staff referred to above indicate the specific risks associated with the use of medical gas in a vehicle.

A prohibition on transporting a patient’s cylinders in a vehicle is reported.

The transport situation is limited to the number of portable cylinders to the quantity necessary for their use during the route.

5.3.3. The residential distribution entity for medical gases informs about the possible incidents that may occur during the use of the equipment as well as the solutions to be adopted.

5.4. Subsequent Deliveries

Subsequent supplies shall be organised in such a way as to ensure treatment at home without any disruption of supply.

5.4.1. At each subsequent supply, the proper functioning of all medical devices associated with the medical gases is tested and, if necessary, the medical devices will be replaced for the use of a single patient.

5.4.2. The competent staff of the home distribution entity for medical gases shall also verify that the conditions of safety and use are met, making any necessary recommendations.

5.5. Handling of emergencies

5.5.1. The entitydistributing medical gases at home shall make available to patients a permanent contactable telephone line twenty-four hours a day, seven days a week.

5.5.2. The telephone service is managed by specialised staff capable of assessing the nature of a call and triggering the necessary intervention.

Chapter VI

TRACEABILITY, COMPLAINTS, RECALLS AND RETURNS

6.1. Traceability

For medical gas, traceability is indispensable in order to ensure that effective batch collection can be carried out.

Cryogenic containers, cylinders and valves shall bear a specific identification number.

6.1.1. The entity which carries out home distribution of medical gases shall be able to rapidly locate the batches of dispensed medical gas, the cryogenic tanks, and the cylinders.

6.1.2. The supply of medical gases to the home distribution entity shall be the subject of a delivery record kept by the home distribution entity for medical gases. This register may be replaced by a computerised system and shall contain the following information:

- Name of the medical gas;
- Date of the fuelling operation;
- distributed volume;
- The name of the home distribution entity for medical gases;
- Batch number
- Date of issue and expiry date;
- Identification of the device and the packaging, as well as the identification of the respective batches
- The name of the manufacturer;

6.1.3. For each home delivery of medical gas made by the home distribution entity for medical gases, a delivery record shall include the name of the patient, the address of the home, the identification of the medical gas made available to the patient, the batch number, the date of manufacture and expiry date, the name of the manufacturer, the verification of the integrity of the device and packaging and the identification of the respective batches, and the quantity delivered. This register may be computerised.

6.2. Complaints

6.2.1. A system for the registration and handling of complaints concerning medical gases and associated medical devices should be organised.

6.2.2. A written procedure should be established describing the actions to be taken, including the possibility of a recall.

6.2.3. Any complaint must be brought to the attention of the pharmacist Technical Director.

6.2.4. All decisions and measures taken in response to a complaint shall be recorded and a report of investigation of the causes shall be carried out.

6.2.5. If a complaint concerns the intrinsic quality of medical gases and or associated medical devices, INFARMED, I.P., the manufacturer of medical gas and the manufacturer of the device must be aware of the complaint.

6.3. Recalls

A system shall be organised for the collection of one or more batches of medical gas, giving the possibility to promptly and effectively withdraw from the market any batch of medical gas which is defective or suspected of being defective, as well as from any defective or suspected defective equipment or device which may be used in connection with medical gases.

6.3.1. The collections are the responsibility of the medical gas manufacturer and all entities that intervene in the circuit including the home distribution entities are responsible for the immediate taking of collection measures, and must undertake quickly and at any time all the actions necessary for the collection.

The Technical Director shall have sufficient staff to handle all aspects of collections with the appropriate degree of urgency.

6.3.2. Written procedures for the organisation of collections shall be in place and regularly checked and updated.

6.3.3. The residential medical gas distribution entity shall inform INFARMED, I.P. of the actions in progress or to be implemented should a possible quality defect or serious quality defect emerge. The collected cryogenic containers and cylinders shall be identified and stored separately pending a decision on their destination. The collection procedure shall be recorded and set out in a final reconciliation report, which shall contain a comparative balance sheet of the quantities distributed and recovered. The effectiveness of the provisions taken should be regularly assessed.

6.4. Returns

6.4.1. The packaging of returned medical gases shall be treated in accordance with a written, risk-based procedure, taking into account the medicinal product concerned, any specific storage conditions and the time that has elapsed since the medicinal product was originally delivered to the patient's home, and there shall be a segregated, delimited and identified area for bottles returned for eventual return to stock.

6.4.2. A returned medical gas package should also be considered as a complaint only if it has been directly linked to an alleged quality problem or defect concerning that medicine cylinder or cryogenic container, in which case it will always have to be referred to the respective supplier.

6.4.3 Packaging of medical gases which have left the distributor's premises shall be returned to marketable stocks only if all of the following are confirmed:

a) The packaging of medical gas is unopened and unaltered, in good condition, and is within the shelf life;

b) It has been demonstrated that the packaging of the medical gases has been transported, stored and handled in accordance with its specific storage requirements and there is no reason to believe that the product has been tampered with or falsified;

c) They have been individually examined, assessed and found suitable for reintegration by the Technical Director, with written acceptance and duly signed and dated.

6.4.4. Products returned to marketable stocks must be arranged in such a way that the ‘first-out, first-out’ system functions effectively.

6.4.5. Stolen products that have been recovered cannot be returned to marketable stock and sold to customers.

6.4.6. The home distributor may choose to consider any returned medicinal product packaging from the patient’s home that cannot be reintegrated in stock, but is only intended for return to the respective supplier, and such option must be described in written procedure.