MEDICAL GASES

GOOD HOMECARE PRACTICE

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1. Introduction

Patient safety is the prime objective of the healthcare industry and each company is required to operate a Quality Management System that is compliant with the basic requirements of the EC legislation. The pharmaceutical EC legislation covering the manufacture and supply of medicinal products (EC 2001/83) specifies that the medicinal supplies shall follow the guidance given in:
Good Manufacturing Practice (GMP)
Good Distribution Practice (GDP)
Good Clinical Practice (GCP)
Good Laboratory Practice (GLP)
In addition the medical devices that are used to provide the therapy to the patient have to be manufactured and used following the essential requirements of the Medical Device Directive 93/42/EEC.
The supply of home oxygen services to patients at home is seen to be an activity that crosses many of the above codes of practice and directives.
Therefore this document defines Good Homecare Practice, which describes the management system requirements for Homecare Service Providers (HSP) in providing home oxygen services.
The format of this document is similar to that of the existing pharmaceutical guidance notes produced by the EC for the healthcare industry.

2. Scope

The document covers the minimum requirements for Homecare Service Providers to perform in order to supply the products, devices and services to the patient at home in accordance with the oxygen therapy prescription and contractual agreements.

3. Purpose

The purpose of the document is to provide a baseline requirement for a Management System for all home oxygen service providers. It is also intended to enable health authorities to regulate and inspect homecare services in a consistent manner.

4. Definitions

For the purposes of this document, the following terms are defined as:

Carer	A relative, friend or professional who assists the patient with their therapy.
Homecare Service Provider (HSP)	An organisation / company that provides the medicinal oxygen and medical devices for treating patients in their home.
Services:	Can mean any combination of: - The installation or removal and replacement, preventative maintenance, repair, reprocessing and technical verification of equipment. - Supply of product. - Providing training, support, advice, and follow-up to the patient. - Providing feedback to prescribers.
Products	Medicinal oxygen.
Equipment	Oxygen therapy related devices e.g. concentrators and disposables e.g. cannulae

5. Good Homecare Practice - Principle

5.1 Principle

The Homecare Service Provider (HSP) shall supply products, services and devices that are fit for their intended use comply with regional/national regulation and do not place patients at risk due to inadequate safety or quality. The attainment of this quality objective is the responsibility of senior management and requires the participation and commitment by staff in many different departments and at all levels within the company.

To achieve the quality objective in a reliable manner, there shall be a comprehensively designed and correctly implemented system of Quality Assurance incorporating Good Homecare Practice and where required Good Manufacturing Practice and Good Distribution Practice.

It shall be fully documented and its effectiveness monitored. All parts of the Quality Assurance system shall be adequately resourced with competent personnel, and with suitable premises, equipment and facilities. There may be additional legal responsibilities for the HSP and for the Qualified Person(s) controlling medicinal products and medical devices, but these are not covered in this document.

5.2 The basic requirements of Good Homecare Practice

The basic requirements of Good Homecare Practice are:

1. All services and supply of equipment and product are assured to each patient in compliance with the therapy prescription and according to the terms of the contract including installation, maintenance and removal of the equipment.

2. All service and supply processes are clearly defined, systematically reviewed in the light of experience and shown to be capable of consistently delivering services, product and equipment of the required quality and complying with their instructions for use.

3. Each patient or carer is adequately trained in the safe and correct use of the therapy equipment and product.

4. All relevant service and supply processes are risk assessed to ensure the safety and health of staff and patients.

   Critical steps of these processes and significant changes to them are well defined, controlled and verified.

5. An organisation chart exists and the responsible individuals are clearly designated.

6. The supplied medicinal oxygen has been manufactured and distributed by authorised companies employing Good Manufacturing Practice and Good Distribution Practice.

7. All the containers and equipment involved in the distribution and therapy are functioning correctly.

8. All necessary facilities for GHP are provided including:

   - Adequate premises and space;
   - Suitable equipment and services;
   - Suitable vehicles and handling equipment;
   - Correct materials, equipment and tools;
   - Approved instructions and procedures, written in an instructional form in clear and unambiguous language, specifically applicable to the activities undertaken.

9. The following measures shall be undertaken:

- All staff are trained and their competency checked to carry out procedures correctly;
- Records are made, which demonstrate that the major steps required by the defined procedures and instructions are taken and that the quantity and quality of the services, product and equipment are as defined. Significant deviations are recorded and investigated;
- Patient identifiable data is handled in accordance with the applicable 'privacy act';
- The distribution of the products minimizes any risk to their quality;
- A system is available to recall any batch of product or equipment from sale or supply;
- Complaints about marketed services, equipment and product are examined; the causes of quality defects investigated and appropriate measures taken to prevent reoccurrence and reports made to the authorities when required;
- There is a procedure for self-inspection and/or quality audits that regularly evaluates the effectiveness and application of this GHP;
- The correct response to emergency situations is ensured according to a pre-established procedure. This procedure shall be effective 24 hours per day, 7 days per week or as specified in a contractual agreement.

6. Personnel

6.1 Principle

All employees dealing with homecare services shall be trained and qualified in accordance with a defined programme incorporating this GHP.

6.2 General

Training requirements shall be the same whether the work is carried out by employees or is sub-contracted to external companies. Staff shall be trained using a referenced training document/package, including both theoretical & "hands-on" training.

EIGA Doc.04 contains relevant training information on 'Fire hazards of oxygen and oxygen enriched atmospheres'.

6.3 Training Requirements for operational staff

6.3.1 Operational staff providing services at patients' home

Basic training shall cover:

- Oxygen risks e.g. fire, cryogenic hazards, oxygen enriched atmosphere, high pressure
- Installation of the therapy equipment
- Removal of the therapy equipment
- Patient/carer training
- Preliminary risk assessment at patient home
- Operation and Servicing of equipment
- Basic clinical understanding of oxygen therapy and patient empathy
- Traceability and recall
- Administrative requirements
- Incident and emergency procedures
- Customer complaint procedures
- Hygienic operations
- Driving skills

- Manual handling skills

6.3.1.1 Specific training when dealing with Liquid Oxygen

Before dealing with liquid oxygen (LOX), staff shall be trained on

- Cryogenics hazards of LOX including effects on other materials
- Lox transport and storage on HSP sites, in vehicles and at patients' homes
- Liquid base units installation and installation checks
- Liquid base units handling
- Working principle of liquid oxygen vessels
- Base and portable unit filling
- Liquid transport

6.3.1.2 Specific training when dealing with Gaseous Oxygen

Before dealing with gaseous oxygen (GOX), staff shall be trained on

- Working principles including accessories and high pressure hazards
- Cylinder transport and storage on HSP sites, in vehicles and at patients' homes
- Cylinder installation and installation checks
- Cylinder handling
- Working principle of pressure/flow regulation

6.3.1.3 Specific training when dealing with Oxygen Concentrators

Before dealing with oxygen concentrators, staff shall be trained on

- Oxygen concentrator working principles
- Concentrator transport
- Concentrator installation and installation checks

6.3.1.4 Specific training when dealing with Other Equipment

Before dealing with other equipment, staff shall be trained on each specific device.

6.3.2 Operational staff performing equipment maintenance:

Basic training shall cover:

- Oxygen risks e.g. fire, cryogenic hazards, oxygen enriched atmosphere, high pressure
- Operation and Servicing of equipment
- Maintenance and repair of equipment
- Basic clinical understanding of oxygen therapy
- Administrative requirements
- Customer complaint procedures
- Hygienic operations
- Manual handling skills
- Traceability and recall

6.4 Training Requirements for customer service staff

The telephone advisers, who handle all types of communication with home oxygen patients, clinicians and other customers, shall be trained on general customer service and specifically on:

- Basic clinical understanding of oxygen therapy and patient empathy
- Oxygen risks e.g. fire, cryogenic hazards oxygen enriched atmosphere, high pressure
- The modalities of oxygen supply – compressed, liquid and concentrator

- Basic function and principles of operation of each of the devices in use
- The information to collect and record before the intervention, as described in § 10.3
- Patient data confidentiality
- Incident and emergency procedures
- Customer complaint procedures
- Traceability and recall

7. Premises

7.1 Principle

Premises shall be located, designed, constructed, adapted and maintained to suit the operations to be carried out. Their layout and design shall aim to minimise the risk of errors and permit effective cleaning and maintenance in order to avoid cross-contamination, build up of dust or dirt.

7.2 General

Premises shall be laid out in order to allow for separation between “dirty” or returned equipment and “clean” equipment ready for supply to patients. There shall be a logical flow between incoming and outgoing equipment to ensure that operations are safely and effectively carried out to plan.
All equipment and oxygen containers shall be secured and protected against adverse weather conditions
Lighting, temperature, humidity and ventilation shall be appropriate and such that they do not adversely affect the storage or functioning of products or equipment.
Premises shall be designed and equipped so as to afford maximum protection against the entry of rodents and other animals.
Steps shall be taken in order to prevent the entry of unauthorised people. Production, storage and quality control areas shall not be used as a right of way by personnel who do not work in them.

7.3 Storage Areas

Storage areas shall be clean and of sufficient capacity to allow orderly storage of the various categories of products and equipment: new, quarantined, released, rejected, returned or recalled.

Storage areas shall be kept clean and dry.
Storage areas for medicinal oxygen packages shall have:

- no combustible material e.g. oil and grease adjacent,
- no heat sources in the vicinity,
- sufficient ventilation to maintain the oxygen concentration in the air to less than 23.5% oxygen in air,
- space and access for “first in, first out” stock rotation,
- marked separation of full and empty containers.

Reception areas shall be designed and equipped to allow incoming products and equipment to be segregated and, where necessary, cleaned before storage.

Segregated areas shall be provided for the storage of rejected, recalled or, returned equipment and products.

7.4 Workshop

The workshop layout shall allow for a logical work flow of incoming and outgoing equipment.
It shall be clean and employ high standards of hygiene.
The tools and instruments that require calibration shall be managed in accordance with a written procedure.

8. Vehicles

8.1 Principle

This section describes the basic design and operational requirements for purpose built vehicles used to transport products and equipment required in a Homecare oxygen therapy service.

8.2 General

Vehicle design and Operation should comply with the IGC 128 document “Design and Operation of Vehicles Used in Medicinal oxygen Homecare Deliveries”

A summary of this document is described below.

Any vehicle design and any distribution and transfilling service shall meet all applicable international/national/local regulations and the conditions of this industry standard.

Any package of gas or cryogenic liquid shall meet all applicable international/national regulations.

Distribution, transportation and transfilling of oxygen shall be performed by trained and qualified personnel in accordance with national regulations.

8.3 The Basic requirements for the design of vehicles

- Compressed and liquid oxygen shall only be carried in a vehicle with adequate ventilation. The cargo compartment shall be suitably ventilated to ensure that any oxygen enrichment of the atmosphere in the compartment is dispersed quickly to keep the oxygen content of the air below 23.5% in normal operation.
- The load shall be secured at all times, during normal driving conditions and under harsh braking. Oxygen shall be segregated from combustible material.
- There shall be a physical separation between the driver’s cab and the load compartment.
- For vehicles transporting oxygen, the cladding of the load compartment shall use non-combustible materials.
- The vehicle design and material selection for the load compartments shall ensure that the vehicle can be maintained in a clean condition.
- The exterior and interior of the vehicle shall be kept in a clean condition.
- The vehicle design shall ensure that the manual handling aspects of loading and unloading of the vehicle can be carried out safely.
- Where the vehicle is used for transfilling from a tank inside the vehicle into patient containers in or outside the vehicle, the vehicle shall be appropriately designed. These tanks, either permanently mounted or temporarily fitted in the vehicle, shall have their:
    - vent lines piped outside the vehicle,
    - main pressure relief valves and bursting discs permanently piped outside the vehicle,
    - vent-relief regulator (where fitted) permanently piped outside the vehicle,
    - bursting discs piped outside the vehicle separately from the other vent lines.

8.4 Specific requirements for the operation of vehicles

- A no smoking rule for driver and passengers shall apply during loading, unloading, and transfilling and in the vicinity of the vehicle. Smoking is not allowed in the vehicle cabin at any time.
- The driver of the vehicle shall be trained in the hazardous properties and in the safe operation of the products carried including emergency procedures.
- The driver shall always wear appropriate clothing and safety shoes. In addition, for transfilling, a face shield and cryogenic gloves shall be worn. All shall be kept clean and grease-free.
- The vehicle shall carry products to clean and disinfect the hands.
- Requirements for Transfilling activities:
    - An adequately trained person shall always remain in attendance during transfilling.
    - When transfilling is carried out inside the vehicle, the vehicle shall remain stationary with the engine off.
    - Transfilling of LOX shall not be done on asphalt, in which case a steel or aluminium plate shall be used.
- All cylinders and tanks, that can be seen from the outside of the vehicle, shall be removed from a vehicle that is parked overnight on the public way or where public have un-restricted access to the vehicle.
- Full and empty containers shall be identified to prevent an empty container being supplied for patient use.
- Dirty and suspected contaminated equipment shall be also identified or segregated to prevent cross contamination.
- Parking shall be done in a safe location where there is no risk to the cargo, e.g., away from heat sources and air-conditioning outlets.
- If parked inside a garage, adequate ventilation of the area shall be ensured. The vehicle shall at all times be locked when parked.
- The preferred location for overnight parking of the vehicle should be at the HSP premises. Where this is not possible, a risk evaluation shall be carried out of the environment to establish a safe parking environment for the vehicle.

9. Documentation

9.1 Principle

Documentation is an essential element of the quality assurance system which covers the Home Care Provider's processes for the company staff (employees and contractors): procedures, checklists, flow charts, data bases, work instructions and manuals.

The documentation shall be designed to allow proper understanding and use of the supplied therapy by the patient.

Any patient related data shall be managed in such a manner as to adhere to the appropriate national/local act on data privacy.

9.2 Essential Documentation

The essential documentation is tabulated here. An adequate version control system and revision process shall be in place. Archiving requirements may vary depending on local regulation.
Documents and records may be either paper or electronic version.

Document types	Content & Purpose	Applies to who	Archiving requirements
Training records	Documentation of specific training activities	Company staff	HR documentation to be kept during employment, and at least for 1 year after eventual termination of employment.
SOPs (Standard Operating Procedures)	Standard Operating Procedures are required for the following topics: - Order intake - Data Management - Incoming goods control - Patient installation & Removal - Risk assessment at patient's home - Maintenance & reprocessing - Deliveries & vehicle operation - Non-compliance and complaints management - Traceability of products & equipment - Recall and Pharmaco/materiovigilance - Self inspection - Training	Standard operating procedures apply to all company staff. Training activities concerning SOP content need to be documented in the appropriate training records.	Significant changes shall be tracked.
SOP related checklists	The SOPs can contain checklists designed for adequate documentation of the activities described in the SOP (order intake form, checklist patient installation, maintenance service reports, non-compliance & complaints document, training records,…)	company staff	Filled in checklists are archived for variable times on a document by document basis. Checklist data can be stored electronically. E.g. patient therapy related documents are kept for two years after end of therapy or decommissioning of equipment.
Equipment Manuals	Manuals contain the necessary information for proper use of equipment	Company Staff, Health Care Professionals, carers and patients	Documentation base of all equipment in use should be archived for proper support. Manuals have to be kept as long as equipment is in use within the patient base.
Patient Database	Patient database containing the necessary tools to perform Home Care Respiratory Service.	Company Staff, prescriber and payer.	Patient therapy relevant data shall be kept for at least two years after end of therapy.
Batch records for products	-Batch labels and records to allow traceability and timely recall	Company staff	As per GMP/GDP requirements
Documentation relating to patient	- Record of risk assessment at patient's home - Training acknowledgement and patient consent forms - other documents stipulated in the contract with Health Care Professional	Company staff	HSP shall archive copies of patient training acknowledgement and patient consent for two years after end of therapy
Support documentation left with patient	This set of documentation contains: - equipment manuals or instructions for use - HSP contact number - emergency contact number - patient role and responsibilities - safety information - delivery notes - Training acknowledgement and patient consent forms - other documents stipulated in the contract with Health Care Professional	Patient, Carer, (Health Care Professional)	N/A

10. Operations

10.1 Principle

Operations shall be carried out in order to fulfil the basic requirements of GHP in 5.2 above.

10.2 General

It is the HSP's responsibility to ensure the patient has the right product and equipment with respect to the prescription and is trained to use it.

In addition there is a duty of care to take all reasonable steps, within the local contract, to safeguard the patient from known risks associated with oxygen therapy such as fire, overuse or under use. The HSP shall also ensure data security and patient confidentiality.

The correct response to emergency situations is ensured according to a pre-established procedure. This procedure shall be effective 24 hours per day, 7 days per week or as specified in a contractual agreement.

It is essential that the HSP's front-line staff have the appropriate skills and training to handle patients /carers' particular needs.

The following documents provide detailed information on the most common supply methods for Respiratory Oxygen Therapy:

- EIGA Doc 89 Medical oxygen systems for homecare supply
- EIGA Doc 98 Safe supply of transportable medical liquid oxygen systems by the healthcare service provider

10.3 Operation process – Receipt of prescription

In the process of setting up a new patient the following information shall be collected:

- Personal Patient data (name, address, phone),
- Invoicing data (Contact name, address),
- Prescriber data (where required - contact name, address),
- Therapy data (flow, hours/day),
- Devices, accessories and disposables needed,
- Access to and within patient's premises.

This information shall be stored in a database. All the data shall be collected and stored in such a way that relevant data protection legislation is complied with, and that patient confidentiality is respected.

10.4 Operation process – Equipment preparation

The following points shall be checked:

- The correct equipment is selected for the prescribed therapy,
- The device and all its accessories shall be clean and prepared for patient use,
- The equipment shall include all the necessary disposables and accessories to start the therapy as per prescriber/customer request.

10.5 Operation process – Patient assessment

A risk assessment for the first installation shall be completed at the patient's premises. EIGA Document 89 gives a typical format.

Risk Assessments are focused in 4 specific areas:

- Access to the home.
- The profile of the patient and the carer.
- The environment in which the equipment will be used.

- The environment in which the equipment will be stored.

10.6 Operation process – first Installation

During the first installation, the HSP shall take care of the following:

- Make sure that devices, accessories and disposables are those suitable for the therapy, in working order and clean,
- Supply back-up, where appropriate or required,
- Make sure that the patient has clear instructions for the safe and correct use of any device,
- Give the patient the right information related to safety and basic troubleshooting,
- Inform the patient and/or caregiver how to contact the Home Service Provider for both routine deliveries and in emergency situations,
- Inform the patient about the treatment of personal data and obtain any necessary patient consent.

The patient/carer shall sign to acknowledge that they understand the training given and that the correct equipment has been received. Where required a copy may be left with the patient.

10.7 Operation process – Ongoing Service

10.7.1 Ongoing supply shall:

- Ensure the patient has sufficient oxygen available at all times according to the prescribed therapy.
- Provide sufficient disposables to the patient (e.g. cannulae, filters) for the safe use of the therapy, or as specified in a contract or as defined by local practice.

Ongoing service may, when required by the contract:

- Measure and monitor patient therapy parameters such as the oxygen usage pattern, and provide feedback to the prescriber.
- Provide for (re)assessment of patient condition following the doctor's requirements e.g. by managing assessment appointments or providing reminders to the doctor.
- Measure and monitor vital signs such as blood pressure, blood oxygen saturation and provide feedback to the prescriber.
- Provide the patient's prescribed need for oxygen outside the home, e.g. travelling.

10.7.2 Information to be collected and stored

- Each time the HSP visits the patient, a record of the visit shall be kept.
- Where required by the contract the HSP may provide the health administrator with brief details of the visit.

10.7.3 Maintenance

Equipment provided by the HSP to the patient shall be maintained in compliance with the manufacturer's instructions and local regulations. Simple maintenance e.g. changing filters may be carried out in the patient's home, but complex procedures such as changing major components shall be carried out by a qualified repairer, approved by the equipment manufacturer where required.

The HSP shall use a reliable system to manage periodic maintenance dates.

10.7.4 Feedback and compliance

There may be a requirement to monitor compliance and react to non-compliance or changes in the patient's condition. This may be provided by the HSP.

Types of clinical and non-clinical feedback may include:

- Oxygen usage compared to prescription.
- Patient activity – e.g. smoking behaviour.
- Mobility – e.g. pulmonary rehabilitation.

10.8 Removal

Equipment removal is necessary when the patient has moved away or when the therapy is no longer required. As soon as the HSP has been made aware that removal is necessary (which shall be authorised by the clinician or contract giver or competent authority, unless the patient has died), an appointment shall be made with the patient's household. Special sensitivity and respect shall be exercised by the front-line HSP staff in the event that the patient has died.

As with supply, a signature shall be received to confirm collection of the equipment.

10.9 Operation process – Reprocessing

10.9.1 Principle

Medical devices used in respiratory homecare applications require an appropriate level of cleaning or disinfection, dependent on their use, but rarely need to be sterile.

Homecare medical devices which have been used by a patient shall be reprocessed prior to reuse by another patient following the manufacturer's instructions and the following principles.

10.9.2 General

Medical devices may be required to be reprocessed in order to bring them to the following states: Clean and Disinfected.

The manufacturer's responsibilities for the reprocessing of medical devices are stipulated in Clause 8 and 13 of the Essential Requirements in Annex 1 of the Medical Device Directive 93/42/EEC.

The reprocessing process of homecare medical devices should comply with EIGA Doc 157 Hygienic Processes for Respiratory Homecare Devices.

10.9.3 Reprocessing Process

Procedures

Cleaning and disinfecting of the device shall always be carried out in accordance with documented procedures. They shall be applied at least to those parts of devices with which patients may reasonably be expected to come into contact. No reprocessing procedures or products shall compromise the correct functioning of the device.

Cleaning and disinfection activities shall be carried out in appropriate areas and under appropriate conditions.

All cleaning and disinfecting agents and reprocessing procedures used shall be verified with regard to their suitability and repeatability with the respective medical device, dependent on the type of use.

Storage

Reprocessed medical devices shall be stored dust-protected and in storage conditions specified by the manufacturer.

To minimise the risk of cross-contamination reprocessed or new medical devices shall be strictly separated from identified contaminated devices in the warehouse and workshop. Separation of contaminated devices may be achieved by suitable packaging, such as with plastic bags.

Contaminated medical devices and parts, including their accessories should be handled with single-use gloves.

10.9.4 Reprocessing Procedure

Cleaning

Cleaning is the physical removal of foreign material (e.g. dust, soil, domestic spillages and organic material) It physically removes rather than kills micro-organisms. It is accomplished with water, detergents and mechanical action.

Following the final step of the cleaning procedure, it shall be checked by visual inspection that no residues either from the previous use or from the cleaning materials are left.

Disinfection

Disinfection is the inactivation of disease-producing micro-organisms. It does not destroy bacterial spores.

Effective disinfection requires that the instructions for the disinfectant, especially with regard to concentration and residence time, are followed.

Functional testing

Following reprocessing, a safety and functional test of the medical device shall be carried out in accordance with the manufacturer's instructions.

11. Service Specifications

The following is a guideline on the service specifications for the Homecare Service Provider to be taken in account in setting up a contractual agreement or regulation.

A specific service to ambulatory oxygen patients is the supply of oxygen therapy service for their activities outside home or during their travel. The practical requirements for such service are described in EIGA Doc 141 Planning Oxygen Supplies for Respiratory Patients when Travelling.

Relevant regulations and quality standards, typically

- Compliance to a Quality Management System
- Compliance to European guidelines: e.g. EIGA industry guidelines
- Compliance to national guidelines
- Medical Device Directive

Patient groups within scope of contract:
For example: COPD, Cystic Fibrosis, palliative (oncology), Cluster Headache, Paediatric, Transplant patients.

Patient needs: specify range of flow rates, hours/day consumption. Specify back-up requirements.

Equipment requirements: Specify that equipment shall meet the clinical needs of the required therapies. In the case of more specific patient needs more detailed specifications may be given.

Disposables: Specify the number and type of disposables (cannula, masks, and tubing) to be supplied.

Clinical: Specify how patients are to be assessed and what clinical decisions, if any, the contractor is required to make. Specify the vigilance requirements for adverse events.

Customer service:

- Describe the service expected.
- Specify frequency of the service when relevant (e.g. patient visit frequency).
- Specify the categories of patient and how billing is to be affected for each.
- Specify the complaint handling procedures and feedback to patients, clinicians and administrators.

Patient confidentiality and Data protection: To be specified in accordance with the local/national privacy act.

12. Complaints, Traceability and Recall

12.1 Principle

All complaints and other information concerning potentially defective products, services and devices shall be reviewed carefully according to written procedures in order to allow for continuous improvement.

A system shall be designed to trace medicinal products and medical devices in accordance with national regulation. A system shall be designed to recall, if necessary, promptly and effectively products and devices known or suspected to be defective from the market.

12.2 Complaints

A structured and documented system shall be in place for effective handling of customer complaints including responsibility for investigation, resolution, feedback to the originator and reporting.

Complaints and non-conformances shall be reviewed regularly for any indication of specific or recurring problems requiring attention and possibly the recall of marketed products and devices.

12.3 Traceability

The organisation shall establish documented means (procedures, processes, tools) for traceability. Such systems shall define the extent of product and device traceability and the records required.
If a product or device defect is discovered or suspected in a batch, consideration shall be given to checking other batches in order to determine whether they are also affected.

12.4 Recalls

A person shall be designated as responsible for execution and coordination of recalls and shall be supported by sufficient staff to handle all the aspects of the recalls with the appropriate degree of urgency.

There shall be established written procedures, regularly checked and updated when necessary, in order to organise any recall activity.

Recall operations shall be capable of being initiated promptly and at any time.

All Competent Authorities of all countries to which potentially faulty products or devices may have been distributed shall be informed promptly.
Competent Authorities shall be informed prior to any recall of products or devices.

The distribution records shall be readily available to the person(s) responsible for recalls, and shall contain sufficient information on wholesalers and directly supplied customers (with addresses, phone and/or fax numbers inside and outside working hours, batches and amounts delivered), including those for exported products and devices.

Recalled products or devices shall be identified and quarantined.
The progress of the recall process shall be recorded and final report issued, including reconciliation between the delivered and recovered quantities.

The effectiveness of the arrangements for recalls shall be evaluated regularly.
The procedures for Pharmacovigilance and Materiovigilance shall comply with national regulations.

13. Self-inspection

13.1. Principle

Self-inspection is part of the quality assurance system and shall be carried out repeatedly with the aim of checking the implementation of and compliance with Good Homecare Practice.

13.2. General

Self-inspections shall be conducted independently and thoroughly according to a procedure written by competent members of the operational staff who are designated for this purpose.

These self-inspections are conducted at regular intervals according to a pre-established programme.

The aim of self-inspections is to check:
- the conformity of the premises and equipment;
- the conformity and updating of documents;
- the conformity of the training level of personnel;
- the compliance with procedures;
- the good adaptation to and compliance with good practices.

The inspections are recorded in a written report, which is signed and dated.

The reports shall include the observations made during the self-inspections and, where applicable, suggestions for corrective actions. A system for following up the implementation of the corrective actions shall be set up and formalised.

14. References

- Council Directive 93/42/EEC of 14th June 1993 concerning Medical Devices, amended by Council Directive 2007/47/EC of 5th September 2007.

- Good Manufacturing Practice – laid down in Directive 2003/94/EC

- Good Distribution Practice – laid down in Directive 92/25 EEC

- Good Clinical Practice – laid down in Directive 2005/28/EC

- Good Laboratory Practice – laid down in Directive 2004/10/EC

- EIGA Doc 04 Fire Hazards of oxygen and oxygen enriched atmospheres.
- EIGA Doc 89 Medical oxygen systems for homecare supply.
- EIGA Doc 98 Safe supply of transportable medical liquid oxygen systems by the healthcare service provider.
- EIGA Doc 128 Design and Operation of Vehicles used in medical oxygen homecare supplies.
- EIGA Doc 141 Planning Oxygen Supplies for Respiratory Patients when Travelling.
- EIGA Doc 157 Hygienic processes for respiratory homecare devices.