# POSITION PAPER

Position Paper PP-34/19 – Revalidation of PP 34 dated March 2011

## Braille Labelling of Medicinal Gas Packages

**Directive 2001/83 EC requires Braille labels to be fitted to all medicinal products supplied to patients for self administration. EIGA believes that fitting Braille labels to medical gas packages will not assist the safety of blind or partially sighted patients when they are prescribed medical oxygen for use at home.**

**EIGA proposes that the medical gas packages, supplied to Homecare patients should be exempt from the requirement to fit Braille labels. However, to meet the intent of the Directive and to promote patient safety for the blind or partially sighted patients EIGA proposes that:**

- **An initial Homecare Risk Assessment be carried out when supplying medical oxygen to each patient at home which should consider and record whether the patient/carer is blind or partially sighted**
- **Where the patient/carer is blind or partially sighted, all information and training should be provided in a suitable format so that the patient can handle and administer the medicinal gas in a safe manner.**

### 1 Introduction

Revisions to the European Directive on Medicinal Products for Human Use, (2001/83 EC) in 2004 introduced new requirements for the labels and leaflets used for medicinal products in order to assist blind and partially sighted patients to administer their prescribed drugs more safely. The changes require the Marketing Authorisation holder to fit a Braille label on all medicinal products supplied to patients for self administration and to provide Patient Information Leaflets in an appropriate format that can be read by blind or partially sighted patients.

Medical oxygen, supplied to patients at home, is the only medicinal gas self-administered by patients. The other medicinal gases supplied to healthcare facilities, are exempt from these changes to the legislation as the gases are administered by healthcare professionals.

There is concern within the medical gas industry that Braille labelling will not add to the safety of blind or partially sighted patients, when administering their medical oxygen at home. This position paper details the industry's proposals for not using Braille labels but providing information and training in an appropriate format in order to ensure blind or partially sighted patients can use their medical gas safely.

EIGA fully endorses the changes to legislation to make the supply of medicinal products to blind or partially sighted patients safer and promotes the following actions for medicinal gases to support these requirements.

### 2 Medical Oxygen Homecare Supplies

Medical oxygen is supplied to patients at home either as a compressed gas in a cylinder or as a cryogenic liquid in a mobile cryogenic container. These packages are very different in shape and size from the other types of medicinal products supplied to patients at home for self administration, such as blister packs or liquids in bottles.

*Fig 1 Typical medical gas cylinder package compared to conventional pharmaceuticals products*

As these medical oxygen packages are relatively large and heavy, there is concern that the Braille labelling may be damaged during the distribution and handling of the packages. This could lead to the meaning of the label changing, causing confusion to the patient. It may also be difficult for blind or partially sighted patients to find the Braille label on the packages, due to the size and shape of the package.



***EUROPEAN INDUSTRIAL GASES ASSOCIATION** AISBL*
AVENUE DES ARTS 3 – 5 ♦ B-1210 BRUSSELS
PHONE +32 2 217 70 98 ♦ FAX + 32 2 219 85 14 ♦ E-mail: info@eiga.eu - www.eiga.eu

As the shape, size and weight of these packages for Homecare supply are very distinctive, it is felt that there is little benefit to fitting a Braille label for blind or partially sighted patients to identify their prescribed medicinal product. The packages also have specific gas connections that are only used when connecting the medical oxygen administration equipment. Hence, there is no risk that they would be confused with other medicinal products.

## 3 Patient Assessment and Training

Homecare patients cannot use their medical oxygen packages without additional equipment to allow them to self-administer the product. To ensure that they can administer their medical oxygen safely when not supervised at home, the Homecare Service Providers are required to carry out a comprehensive Homecare Risk Assessment at the patient's home prior to supplying the gas.

The Homecare Risk Assessment covers an evaluation of the premises, where the product will be used, and an assessment of the patient to ensure that they are competent to both handle the medicinal gas packages and administer the gas safely. The assessment requires the Homecare Service Provider to assess whether the patient (or carer responsible for administering the gas) is competent to use the gas safely and physically capable of operating the equipment. As a part of this assessment, it will be noted in the patient's record whether they are blind or partially sighted and that their disability does not put them at risk when handling the product. When the assessment is carried out, the Homecare Service Provider will also provide the patient with the Patient Information Leaflet in the appropriate format. This will be noted on the Homecare Risk Assessment and recorded on the patient record.

EIGA has prepared a generic Risk Assessment Form for both identifying the main hazards in the property and for recording the results of the competency assessment carried out with the patient and/or carer. The form is available in MGC Doc 89 (Medical Oxygen Systems for Homecare Supply), which may be found at www.eiga.eu.

## 4 Patients Follow Up

As part of the service, the Homecare Service Provider periodically visits patients to supply new medical oxygen packages and to verify that the patient's equipment is operating correctly.

During these visits, all patients are reassessed to ensure that the home environment is satisfactory and that the patient can operate the equipment competently. As part of this reassessment, blind or partially sighted patients will be checked to ensure that they do not require any re-training.

## 5 Conclusions

Although the Directive 2001/83 EC requires Braille labels to be used for all medicinal products supplied to patients for self administration, the Medical Gas Industry believes that it will not assist the safety of blind or partially sighted patients when they are prescribed medical oxygen for use at home.

EIGA proposes that medical gas packages should be exempt from fitting Braille labels.

To meet the intent of the Directive, EIGA proposes that:

- the initial Homecare Risk Assessment carried out when supplying medical oxygen to patients at home should consider and record whether the patient/carer is blind or partially sighted, and
- where the patient/carer is blind or partially sighted, all information should be provided in a suitable format so that the patient can handle and administer the medicinal gas in a safe manner.

Individual gas companies or the National Gas Associations may contact the National Association for the Blind, to request assistance in preparing dedicated information where necessary.

Where the National Regulatory Authority requires confirmation of the suitability of the approach taken by the gas industry, the National Association of the Blind may be used to help endorse this approach.

Some National Regulatory Authorities have already indicated that all medicinal gases are exempt from the requirement of Braille labelling, including Homecare packages.