Notification Number: 1999/371/F

Order concerning good practice when dispensing oxygen for medical use at home.

Date received	:	28/07/1999
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Issue of comments by	:	United Kingdom

Message

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Message 002

Communication from the Commission - SG(1999) D/51759
Directive 98/34/EC
Translation of the message 001
Notification: 1999/371/F

(MSG: 199901759.EN)

1. Structured Information Line
MSG 002 IND 1999 0371 F EN 29-10-1999 28-07-1999 F NOTIF 29-10-1999

2. Member State
France

3. Department Responsible
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4. Notification Number
1999/0371/F

5. Title
Order concerning good practice when dispensing oxygen for medical use at home.

6. Products Concerned
Oxygen for medical use which corresponds to the definition of a medicine;

7. Notification Under Another Act
-

8. Main Content
This code of good practice on home dispensing aims to define the conditions under which oxygen for medical use must be administered at home.

This code defines:
-a system of quality control ensuring that technical measures and an organisational pattern are established for the proper supply and dispensing of gases;
-the role of the pharmacist in dispensing;
-the implementation of safety guidelines pursuant to the prevailing regulations;
-rules for home dispensing;
-rules on follow-up enabling treatment to be repeated where necessary;
-the rules concerning sub-contracting.

This code of good practice on home dispensing of oxygen for medical use is a technical guide which primarily concerns industrially produced oxygen (in liquid or gas form), delivered in bottles or in an evaporator. However, it also concerns oxygen derived from concentrators - medical equipment which, when set up in the home of the patient, supplies oxygen by using the surrounding air as its source.

This guide applies to legal entities as referred to in Article L.512-2 of the Public Health Code (associations and businesses), and in accordance with French common law, to mutual benefit pharmacies and miners' pharmacies as well as to dispensaries.

9. Brief Statement of Grounds
The designation of gases for medical usage as medicines has recently been recognised by the Ministry of Health. The recognition of this designation has led to three consequences which concern:

-issuing authorisations for the placing on the market of oxygen delivered in a bottle or in an evaporator.
-issuing authorisations relating to the opening of pharmaceutical establishments for manufacturers of gas for medical use;
-retail dispensing. In 1996, a legal amendment to the Public Health Code (article L.512-2) entitled outlets other than dispensaries to dispense gas for medical use.

In actual fact, the home dispensing of oxygen has for several years been guaranteed by legal entities which are:

- on the one hand, associations, under the umbrella of the federation Antadir (Association Nationale pour le Traitement à Domicile de l'Insuffisance Respiratoire Chronique, i.e. National Association for the Home Treatment of Chronic Respiratory Insufficiency),
- on the other hand, either companies which are generally subsidiaries of pharmaceutical wholesale distributors, or companies made up of dispensaries; all of the above companies are united within Usdifamed (Union Syndicale des Distributeurs de Fauteuils roulants et appareils médicaux, i.e the Trade Union of distributors of wheelchairs and medical equipment).

These companies and associations which deliver oxygen for medical use to patients' homes will be able to continue to do so provided they have been authorised and that they respect the code of good practice.

The draft guide which has been submitted for your attention was therefore written by the Ministry of Employment and Solidarity, in close collaboration with the professionals in question (Ordre des pharmaciens, Antadir and Usdifamed).

10. Reference Documents - Basic Texts
a) List of basic texts

Extract of Book V of the Public Health Code, and in particular the following articles hereof: L.511, L .512, L .512-2 (Article 21 II of Act no. 96-652 of 28 May 1996), L . 568 ,L .596, L.598, L.601, L.665-3, R.665-1.

Guidelines concerning the demarcation between Directive 90/385/EEC relating to active implantable medical equipment, Directive 93/42/EEC relating to medical equipment and the Directive 65/65/EEC concerning pharmaceutical specialisms and the related Directives.

b) -

c) -

11. Invocation of the Emergency Procedure
No

12. Grounds for the Emergency
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13. Confidentiality
No

14. Fiscal measures
No

Carlo Trojan
General Secretary
European Commission