

SELF-MEDICATION IN EUROPE

Common Position of the CP, UEMO, UEMS and AESGP

27 February 1997

INTRODUCTION

In June 1994 the European Commission issued a Communication on a programme of Community action on *health promotion, information, education and training* within the framework of action in the field of public health (COM (94) 202).

In this Communication¹ it was recognized that European citizens wish to take more responsibility for their own health and that a large number of messages on self-medication are transmitted through the media.

The Commission also emphasized that advice and information given to consumers should ensure that self-medication is appropriate, safe and responsible.

This document provides the consensus views of European doctors and pharmacists and the manufacturers of non-prescription medicines on how this can be achieved.

DEFINITIONS

Self-medication is the use by patients, primarily on their own initiative and under their own responsibility, of non-prescription medicines with the optional assistance or advice of pharmacists or other health professionals.

Evidently, medical doctors may also provide information on non-prescription medicines.

Self-medication only has the potential to help prevent and treat symptoms and ailments which do not require medical consultation.

The right to make a medical diagnosis is restricted to medical doctors.

Prescription medicines are defined in directive 92/26/EEC (Article 3.1) as follows:

“Medicinal products shall be subject to medical prescription where they:

¹ Communication from the European Commission concerning a programme of Community action on health promotion, information, education and training within the framework for action in the field of public health (COM (94) 202 final) of 01.06.1994

- *are likely to present a danger either directly or indirectly, even when used correctly, if utilized without medical supervision, or*
- *are frequently and to a very wide extent used incorrectly, and as a result are likely to present a direct or indirect danger to human health, or*
- *contain substances or preparations thereof the activity and/or side effects of which require further investigation, or*
- *are normally prescribed by a doctor to be administered parenterally.”*

According to Article 4 of this directive, “*Medicinal products not subject to prescription shall be those which do not meet the criteria listed in Article 3.*”

OBJECTIVE

All parties associated with self-medication must seek to ensure that all medicines supplied without medical prescription are appropriate for the user and that sufficient and relevant information is given to provide maximum therapeutic benefit and safety in use.

PROFILE CRITERIA FOR SELF-MEDICATION

1. Self-medication is related to symptoms and not to medical diagnosis.
2. The parties fully support the provisions in European legislation which require safety, quality and efficacy to be proved before a marketing authorization for a medicinal product, including a medicine to be available for self-medication, is granted in any Member State or at European level.
3. Advertising and promotion for non-prescription medicines shall comply with Community legislation and effective ongoing measures should be taken to ensure compliance with the standards.
4. Self-medication is suitable for symptoms and ailments which do not require medical consultation.
5. The period for which self-medication is appropriate will vary according to circumstances, but should not normally be longer than three to seven days.
6. Self-medication is not appropriate and the individual should consult a medical doctor in the following situations:
 - symptoms have persisted
 - a condition worsens or recurs worse than before
 - severe pain
 - one or more medicines which appear to be appropriate for treatment of the condition have been tried without success
 - suspected adverse reactions to prescribed or non-prescribed medicines occur
 - symptoms are recognized to be serious
 - psychiatric problems co-exist, e.g. anxiety, unease, depression, lethargy, agitation or hyper-excitability.

7. Specific attention should be paid to certain groups, such as pregnant or breastfeeding women, babies and infants.

SITUATIONS

The following are some of the situations which may be appropriate for the purposes of self-medication provided the criteria above are met:

- colds, influenza
- cough
- sore throat
- recurrent allergic rhinitis (including hayfever)
- mouth ulcers
- indigestion (including heartburn)
- constipation
- vomiting and diarrhoea
- haemorrhoids
- sunburn
- warts
- mild to moderate pains such as headaches and muscular pain.
- mild to moderate skin problems

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