AESGP
Association Européenne des Spécialités Pharmaceutiques Grand Public
Association of the European Self-Medication Industry
Europäischer Verband der Arzneimittel-Hersteller

AESGP Comments on the Commission Consultation on a legal proposal on information to patients on medicinal products

Introduction

AESGP represents the manufacturers of non-prescription medicines in Europe.

The provision of information to patients is recognised as an important area for consideration for all medicinal products, both prescription and non-prescription. Therefore, although the Commission's current consultation "on a legal proposal on information to patients" states that "the revision should clarify the rules on information provided by pharmaceutical companies on prescription-only medicines", AESGP wishes to take this opportunity to highlight some issues with respect to the regulation of non-prescription medicines on which clarification would be useful.

Changes in society such as access to the Internet mean that patients / consumers have become more empowered and that they are actively seeking more information regarding available treatments for their illnesses. The Commission initiative to consider a Community framework to support the provision of information to patients is welcome, especially in the context of current health challenges such as obesity and smoking addiction and the encouragement by many health systems to adopt a partnership approach with the patient / consumer.

The High Level Pharmaceutical Forum has identified as a key concern that Member States may not be in a position to address patients' needs in terms of substance of information via the Internet. It has been noted that the pharmaceutical industry possesses key information on products, but that this information cannot be made available consistently. There are good reasons to change this situation.

Since non-prescription medicines may be advertised to the patient / consumer, it may appear that pharmaceutical companies can provide information to the public as appropriate, and that there are consequently no major issues or concerns with the current situation in connection with non-prescription medicines. This is, however, not completely true: opportunities exist to further enhance the possibilities of how information on non-prescription products can be provided to consumers. We would therefore like to encourage the Commission to consider a specific dialogue in this area along the lines set out in the following pages.

7, avenue de Tervuren • B-1040 Brussels • Belgium • Tel.: + 32 (0)2 735 51 30 • Fax: + 32 (0)2 735 52 22
E-mail: info@aesgp.be • http://www.aesgp.be

Suggestions for amendments of current practices

1. Information on the outer packaging

Article 62 of Directive 2001/83/EC as amended states that the outer packaging and the package leaflet may contain symbols and pictograms which are useful to help the understanding of information aligned to the summary of product characteristics **"…to the exclusion of any element of a promotional nature"**. This text applies to prescription and non-prescription medicines alike.

The notion "promotional nature" is however not defined. Therefore the application of what is - and is not - allowed on the outer packaging of non-prescription medicines varies within the Member States (see case study below for an example). Yet the content and design of the pack are considered as part of the marketing authorisation, and are therefore controlled by the formal marketing authorisation procedures.

Case study: Voltaren®

The global branding of Novartis OTC's Voltaren® (pain relief/anti-inflammatory) uses a 'stretching figure' on the logo, identifying the product with its effect.

This is not permitted in Sweden, where a 'tick' has to be used instead.

The recently adopted Revision 5 of the EMEA Guideline on the acceptability of invented names for human medicinal products processed through the centralised procedure makes a distinction between prescription and non-prescription medicines, and states that "In order to help self-selection and compliance by patient/consumers, it is acceptable that (invented) names have a positive connotation and/or be informative". In view of this, it would be useful to clarify that symbols and pictograms can also convey such a positive connotation.

In a wider context, the practical consequence for non-prescription medicines of the current legislation is that information to consumers beyond the patient information leaflet can be provided via booklets, Internet sites, etc., but that it cannot be placed on the outer packaging. Moreover, there are situations where a product can be placed on a shelf and an information booklet providing helpful information on the condition treated by the product can be placed next to the pack on the shelf, but where the consumer has to pick up the items separately. From a consumer perspective, this seems to place an unnecessary barrier on the way to access to information.

In addition, advice on a category such as smoking cessation may be made available on a website but the link to the website cannot be placed on the pack. To illustrate this, the product NiQuitin® from GlaxoSmithKline Consumer Health (GSK), which belongs to the category of Nicotine Replacement Therapies for smoking cessation, contains advice in the Summary of Product Characteristics that "behavioural support is beneficial". GSK offers such support as an on-line personalised stop-smoking plan called Click2Quit (click2quit.com). To enrol, however, quitters need to make a telephone call to obtain the web address. This seems an unnecessary restriction when placing the web address on the outer packaging would be more convenient and could indeed assist compliance.

Given that non-prescription products may be advertised to the general public, the restrictions mentioned above do not seem logical. A pragmatic approach is therefore necessary for non-prescription medicines where informative graphics and symbols, booklets and web addresses can be of benefit to consumers, especially in the current environment where self-care is being promoted at different levels. Consequently, AESGP is of the opinion that self-medication companies should be allowed to include web addresses on the outer packaging as well as other useful information in the patient information leaflet and inside the outer packaging.

2. Control of advertising materials

Information to patients on non-prescription medicines is usually related to a specific product (there being little incentive to provide unbranded materials) and is therefore considered as advertising. These advertising materials are subject to a variety of national control systems which in general appear adequate. However, as the material content must be consistent with the terms of the marketing authorisation but the specific content is not part of this authorisation (in contrast to the information on the outer packaging and in the leaflet), a gap could exist in how information to patients provided as part of the pack (or via a website) is controlled.

AESGP would suggest that there is now an opportunity to establish a framework for the provision of information to patients / consumers that would specifically enhance the practical realities with regard to non-prescription products in light of the basic premise that non-prescription medicines can be advertised to the general public.

We would therefore suggest re-considering the way of applying Article 62 of Directive 2001/83/EC as amended with regard to the definition of "promotional nature" with respect to non-prescription medicines, so that a practical solution can be found to allow consumers to access information through the most obvious vehicle, i.e. the text on the outer packaging. This would require a balancing of appropriate control mechanisms (i.e. that of the marketing authorisation versus that of advertising materials). The current consultation on the development of the Commission proposals on a framework for information to patients would seem to provide an opportunity to explore such an avenue in order to help consumers / patients manage their health.

Status: 4 April 2008