COMITÉ PERMANENT DES MÉDECINS EUROPÉENS
STANDING COMMITTEE OF EUROPEAN DOCTORS

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At the CPME Board Meeting in Brussels on 13 June 2009, CPME adopted the following document "**CPME position on the proposal for a Directive on the provision of information to the general public on medicinal products subject to medical prescription**" (CPME 2009/112 final EN/Fr)" (referring to CPME 2009/112 EN/Fr)

CPME position on the proposal for a directive amending, as regards information to the general public on medicinal products subject to medical prescription, Directive 2001/83/EC on the Community code relating to medicinal products for human use

CPME notes with satisfaction that the scope of the present proposal for a Directive on information to patients has been reduced to the original goal defined at the Pharmaforum, information about medicines. The necessary harmonised framework for provision of information by marketing authorisation holders about their prescription-only medicines to the general public does not include provision of information about diseases anymore. CPME has argued repeatedly that the inclusion of information on diseases would represent a task of herculian proportions.

The aim of providing information about the benefit and risks of medicines through marketing authorisation holders (pharmaceutical industry) in an understandable, objective and non-promotional format, does raise a few questions which CPME would like to raise by this present position.

CPME also notes with satisfaction that one of the major declared aims of this proposed Directive is to provide information in such a way that the different needs and capabilities of individual patients are addressed in an equal manner. By addressing the provision of information primarily through the internet though, this might prove contrary to the goal of equal access of all citizens. In order to obtain health literacy, citizens have to become internet literate first and preferably in the English language. Is the aim then solely a declared one?

Monitoring and enforcement measures destined to ensure that the information providers (market authorisation holders) comply with the established quality criteria, should primarily guarantee that the very thin line between objective information and promotional advertising is clearly identified and that the existing and future ban on direct-to-consumer advertising is vigorously enforced. CPME wishes to emphasize once more its' absolute opposition to direct-to-consumer advertising, be it in individual, generalised, direct or indirect formats.

The amendment of Directive 2001/83/EC and Regulation EC N° 726/2004 aims to regulate and harmonise pharmaceutical legislation as regards to the provision of

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information to the general public on prescription-only medicinal products of human use. Although CPME recognises the fact that industry should know its' products best and should have the right to provide objective and verifiable information about its' products, this should not represent the only information channel available to end-users. CPME recommends that links to recognised and validated evaluation organisations or agencies should be included in the information packages. Easliy recognisable and identifiable links to product-relevant pharmacovigilance information should also be made available to the end-user.

One of the quality criteria that should be monitored and enforced concerns the completeness of the information. Providing objective, verifiable and validated information is not enough as the most important criteria to fulfill concerns the completeness of the information. Saying the truth is nice, but it is much nicer to say all the truth.

We have seen through numerous past examples how industry is bypassing direct-to-consumer advertising by so-called public interest campaigns which tend to put pressure on health care officials, health care professionals and patients alike. Without advertising a specific product, the campaigns promoting the use and reimbursement of HPV (human papilloma virus) vaccines have proven that industry can very well go into advertising mode on prescription medicines. For these cases a European Agency should be able to intervene after convening an ethical board in order to treat complaints about these types of issues (such as the Pharmaceutical Committee in decision 75/320/EEC). This power of intervention should also comprise sanctions.

CPME maintains that even though patient autonomy calls for diverse sources of information coming from industry or national competent authorities, amongst many others, the main source of information remains the health care professional through the privileged patient-doctor relationship. It is through this individual, intimate and confidential contact that available information can be transformed into patient knowledge. In these times of information overkill the invidualisation of information, tailored to the needs and requests of the individual patient is of foremost importance.
The proposed Directive aims at making disseminated information to patients compliant to a set of quality criteria. It also calls for the definition of the types of information to be diffused. *("it is appropriate to allow marketing authorisation holders to disseminate the contents of the approved summaries of products characteristics and package leaflet, information that is compatible with those documents without going beyond their key elements, and other well-defined medicinal product-related information").* This information should be provided through specific channels of information only, including Internet and health-related publications and excluding such media as television and radio. As the Internet allows unlimited transborder access, the Directive calls for specific monitoring rules through cooperation between the Member States.

"Quality criteria", "other well-defined medicinal product-related information", "health-related publications" and "transborder internet site monitoring" are all suffering from the same problem: a lack of precision and definition although the amendments do offer a certain level of clarification. CPME would like to draw attention to the fact that this lack

of precision or definition applies to some of the key elements for the implementation of the proposed Directive and introduces probably too much leeway for interpretation.

Concerning the monitoring and registration of web-sites of marketing authorisation holders with the national competent authorities of the Member State, CPME would like to know how and if the Commission thinks to regulate the case of non European Union websites of these same market authorisation holders. Even if direct-to-patient and comparative advertising is not allowed by European legislation, it takes only a few clicks and the European citizen can find a different kind of information about the same medicine in a non-EU country site by the same provider or manufacturer.

Even if the proposed regulatory framework of this proposed Directive is seeking to clarify some aspects of the Information to Patients debate, CPME is reluctant to accept this as a guarantee that marketing authorization holders will respect the initial goals of handing out only verifiable, validated and objective information without drifting into advertising or direct-to-consumer marketing. The important aspect of patient information should not be left to industry alone.

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