Public Consultation on the EC Legal Proposal on Information to Patients

Answer sent by ANF – National Association of Pharmacies (Portugal)

1. Introduction

The Portuguese **National Association of Pharmacies** (ANF) has by mission the protection of the common interests of the legal owners of community pharmacies, whom ANF represents, supporting them in the social-political, professional, economic, financial and fiscal domains, as well as the protection of the common interests of the population, in particular of patients.

Founded in 1975, the Association has 2 692 members (97% of the total number of community pharmacies).

The Portuguese pharmacies are units integrated in the national healthcare system, with permanent technical direction provided by pharmacists.

The promotion of public health and patient information are essential fields of the pharmacist intervention in the community. Therefore, an informed dispense of medicines that promotes adherence to therapy and assures patient safety assumes special importance in the daily contact of the pharmacist with the population.

ANF welcomes the opportunity to answer to the European Commission's consultation on a future legislative change on information to patients relating to prescription-only medicines (POM). Following the consultation processes undertaken during 2007, to which PGEU[1] has answered and to which ANF as its member has contributed, and the parallel ongoing impact assessment to which ANF has also contributed on January 2008, this Association has always shown deep concerns about this forthcoming initiative and is very sceptical concerning the proposals presented in this particular public consultation.

2. Quality Criteria & Information Validation

ANF has a critical view concerning the value added of the pharmaceutical industry's role while provider of non-promotional information directly to patients on medicines and the diseases which they treat, and how this could influence patient behaviour.

One of the main policy objectives announced for the forthcoming proposal is the maintenance of the ban on direct-to-consumer advertising of prescription medicines, in compliance with the established by the article 88 of Directive EC/27/2004. However, the ***distinction between advertising and non-promotional information is not clear***, especially when analysed the type of actions allowed by providers, namely the means and format.

[1] The Pharmaceutical Group of the European Union (PGEU) is the European association representing community pharmacists in 30 European countries.

The Commission has included the quality criteria approved by the members of the Pharmaceutical Forum, to which the information to the public must obey, although the criteria of **"unbiased" was neglected when substituted several times by the quality criteria of "non-promotional"** with a weak definition, stating that "information should "focus on guiding patients to the correct use of medicines". This fact raises concern and apprehension that the borderline between advertising and information to patient on prescription only medicines, if exists, is very subtle.

Despite the Commission considering that the information provided should not go beyond the key elements of approved SPCs and PILs, the consultation also covers other sources of information such as scientific studies. It is well known by the public the considerable influence of the pharmaceutical industry in this area, as the financing of these studies is usually done by the pharmaceutical companies, creating a clear problem of lack of exemption.

Besides, the forthcoming proposal does not foresee a system of contents' validation and the only substantial duty to the national co-regulatory body will be the notification of activities regarding the provision of information to the public. The Commission's proposal opens the door to the pharmaceutical industry to have at its disposal a wide range of possibilities to provide or push information to patients, an hypothesis that ANF totally disagrees with.

In this scenario it is crucial to maintain the public confidence in the integrity of the information provided. Though, besides complying with the quality criteria, the non-promotional information must be subject to previous validation.

ANF has a strong opinion regarding the **importance of advance validation** of the **information to citizens** that a market authorisation holder would like to provide. This validation should be made **by an independent body**. Therefore, we believe this process of validation should be made preferably by a regulatory body.

The accessibility to information by the citizen/patient does not constitute an additional benefit to patient adherence to therapeutics or to an early diagnosis. The value added would rely **on the possibility for the patient to discuss** this information **with a healthcare professional** and **on the follow-up done by the healthcare professional of this particular patient**.

This consultation seems to overlook the benefit and interest of the patient and it gives the impression that it looks forward to open the scope of commercial freedom to the pharmaceutical industry.

3. Sanctions

In case of non-compliance to the quality criteria, it is foreseen a system of sanctions, the first being just public embarrassment, followed by possibly fines for "repeated and severe cases of non-compliance". Not only this system appears to be weak, but also issues of conflict of interests arise regarding its application because the pharmaceutical industry is included as a full member of the national co-regulatory body.

The Commission possibly understands that the participation of the industry in this entity is justified by the fact that the industry has a collective interest in assuring that its members do not infringe the rules, because that would harm its overall image and give the infringer a competitive advantage. Nevertheless, what may happen is the prevalence of the collective interest of the industry in weakening the rules of provision of information, as a strategy to make the sanctions' system less effective.

In our view, this proposed system is too close to a self-regulation system, which is not a viable solution to maintain the current level of patient safety that the current legislation ensures. Conflict of interest is inherent to this option.

Moreover, the proposed structure for monitoring foresees an Advisory Committee that has no powers at all. The committee could provide advice but could not compel. Besides, it could not provide a scientific assessment, as stated in the consultation. So, what useful advice could it provide, if even the interpretation of the law ultimately belongs to Courts?

4. Conclusion

We would like to express to the European Commission our apprehension on the strategy put forward in this subject. We find difficult to believe that it may constitute a solid basis upon which the Commission can build a legislative proposal. Overall, what is presented in this consultation is a future scenario where the industry can freely "communicate" about its products in the mass media and in the Internet, with no validation system, where sanctions are practically inexistent or have no true impact, and with a weak system of quality criteria.

The **current legislation** on accessibility and provision of information to patients **protect public health** providing a framework that looks for ensuring non-promotional, objective and unbiased information on medicines.

The **European Commission must protect the right of European citizens to independent, impartial information about healthcare in general and medicines in particular**. Citizens/patients should be **advised by health specialists who have an overall knowledge on diagnosis and treatment possibilities**, not by the inevitably narrow view of the pharmaceutical industry.

There is an obvious conflict of interest in pharmaceutical companies providing information directly to patients.

ANF believes that **public interest and public health should come first**, urging the Commission not to allow the pharmaceutical industry to provide so-called non-promotional information to the public. It should rather ensure that the current channels of information using health professionals are strengthened.