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Main Association of Austrian Social Security Institutions

Comments on the European Commission Public Consultation on a Legal Proposal on Information to Patients

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Introduction

The Main Association of Austrian Social Security Institutions, which covers amongst other things the health insurance of almost all Austrian citizens, appreciates the possibility to contribute to the proposal on information to patients by the Commission.

Unfortunately, the recent proposal by the Commission gives the impression that the main issue is not the needs of patients but sales promotion of pharmaceutical products.

How is it, for example, to be explained that the term "unbiased" – one of the Core Quality Criteria fully acknowledged by the Pharmaceutical Forum and therefore by all stakeholders – has been excluded from the main policy objectives quoted in the proposal? The definition of "unbiased" is comprehensive and, thus, covers many important requirements for patient information:

- Unbiased refers to the elaboration of high-quality patient information; it takes into account all available sources (exhaustive) of information relevant to the area (notably positive and negative studies).
- Unbiased content needs to be impartial and free from conflict of interest (disinterest) and does not reflect (directly or indirectly) the individual objectives of the provider; it must allow the reader to formulate his own opinion.
- Unbiased wording is non-directive and does not use words that appeal to emotions – fear, creating a need, unrealistic hope, promise.

Given the exclusion of the term "unbiased" and its replacement by the non-committal term "non-promotional", could it be that the Commission does not want to pursue all these requirements?!

Target group

Article 88a of Directive 2001/83/EC, introduced by Directive 2004/27/EC, called upon the Commission to present a report on current practices in Member States with regard to information provision for patients on medicinal products. All drafts brought forward by the Commission so far, however, focus on citizens and/or consumers, which seems rather inappropriate and runs the risk of so called "disease mongering". This term is used to describe the attempt by pharmaceutical companies to promote non-existent diseases and to exaggerate mild problems to boost profits. Therefore, according to the intentions of the Directive patient information should be strictly illness-related and aim at patients already diagnosed.

Equal accessibility

The basis of all proposals by the Commission is the claim that there are inequalities between Member States with regard to access to information and that all EU citizens have the right to high quality information. Although we have to admit that people who

do not speak English or are not computer literate have fewer options for information these facts do not justify direct industry involvement in the pushing of information. Moreover, these inequalities do not only occur between Member States but also within them.
Identifying existing barriers and finding ways to overcome them would be a much more appropriate approach for solution to this problem. In this respect health professionals should remain the primary resource of easily accessible and reliable information to patients.

Information versus advertising

One of the crucial objectives of the proposal is “making sure that there is a clear distinction between advertising and non-promotional information” so that under “the clear safeguard all advertisement is banned” the pharmaceutical industry should be allowed to disseminate information on prescription-only medicines through TV, radio programmes and print media. Unfortunately, there is no clear distinction between information and advertising and the distinction between so called pull-mechanisms (information sought actively) and push-mechanisms (information received passively) is by no means a suitable instrument for the purpose in question.
Ex-ante validation is not intended, only the obligation to inform a national co-regulatory body about planned activities. Sanctions will be imposed retrospectively, once the “information” has been disseminated and taken in by millions of citizens. They may range from mere public embarrassment to fines for repeated and severe cases of non-compliance. This is completely unacceptable since benefits from dissemination of promotional information are likely to outweigh any fine by far.

Role of the pharmaceutical industry

The main objective of the pharmaceutical industry is making profit. Thus, information provided by the industry is per se promotional.
One of the reasons brought up by the Commission why the pharmaceutical industry ought to be involved in the process of providing information to patients is the claim that industry is the main source of information. Experience, however, has proven that the industry is not always willing to share all information – especially in the case of negative study results.
Furthermore, a pharmaceutical company is unlikely to provide equal information on all therapeutic alternatives available or to recommend a rival product if there is better evidence for it. Consequently, it is to be feared that patients will be inundated and confused with so much diverse information that they will not be able to decide which information they can and should rely on – the exact opposite of what the Commission set about doing.

Control mechanisms

The Commission relies strongly on the pharmaceutical industry to abide by the Core Quality Criteria developed and acknowledged by the Pharmaceutical Forum in 2007.
But experience of direct-to-consumer advertising in the USA and of direct-to-doctor advertising in Europe provide many examples of pharmaceutical companies bending objectivity and truth among which we would like to give just one as a model:
A systematic review of 103 advertising spots in US-television showed that 58% were valuated as a medical breakthrough. Independent evaluation came to the conclusion that 63% of the mentioned products were mee-toos or even controversial therapies. In total, the investigation covered 24 pharmaceuticals, one of them (Tegaserod) was meanwhile withdrawn from the market because of serious undesired effects. Aggressive advertising is assumed to be the main reason for Tegaserod being listed among the 200 pharmaceuticals most popular in the USA in 2005.

The Main Association of Austrian Social Security Institutions welcomes the development of the Core Quality Criteria as a useful instrument for assessing information to patients and for distinguishing high quality information from poor quality information. However, national authorities cannot simply rely on the pharmaceutical industry to adhere to them for obvious reasons.
Although the proposal rejects sole self regulation, validation prior to dissemination is also ruled out because the Commission puts it on a par with “unnecessary bureaucracy” and favours so called co-regulation. Under this system, the absurd situation will occur that the pharmaceutical industry itself, which is to be part of this body according to the proposal, will take part in the decision whether fines are imposed on the pharmaceutical industry. Moreover, it has to be considered that patient information is a very delicate issue and that different pieces of information from various pharmaceutical companies could cause uncertainty among patients and do a lot of harm. Therefore, a certain amount of bureaucracy seems to be justified in this case.

If the pharmaceutical industry is to be included in the process of generating information for patients at all, the only acceptable alternative is as part of a Public Private Partnership (PPP) of all stakeholders. This requires a number of rules and procedures but at least there are examples of working PPPs in Member States. However, the evaluation of information prior to its dissemination (ex-ante control) by a national authority is in any case essential!

Conclusion

Not only must the existing ban on direct-to-consumer advertising be maintained, it must not be undermined or evaded under any circumstances.

High quality patient information should be generated by official independent bodies within a defined process including validation by national authorities prior to dissemination.
Future activities at EU level should focus on a system of collaboration between Member States to facilitate the exchange of existing good practice.