Agenzia Italiana del Farmaco

AIFA

Italian comments on Proposal on Information to Patients

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This document aims to report comments, remarks and suggestions developed by the Italian Medicines Agency (AIFA) on the information to patients proposal related to the public consultation promoted by the DG Enterprise and Industry. In Italy, AIFA is the national regulatory body deputed to the vigilance and the approval of all promotional activities provided by pharmaceutical companies on prescription medicines.

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1. Preamble

In 2001 the European Parliament (EP) rejected direct-to-consumer advertising of prescription medicines by the pharmaceutical industry, in Article 88a of the Directive 2001/83/EC. Through the same Directive, the European Commission (EC) was called upon by the EP to analyze the different processes in European countries and to draft proposals, in order to define useful strategies to get good quality, reliable and non promotional information. In 2007, on the website of the Directorate-General Enterprise & Industry a document was published; it reported different rules and practices on drug information in European Member States (MS). One of the problem rising from this document is the multiplicity of the approaches of MS and the subsequent differences in the access to information by European citizens. The quality of information is currently very variable, in particular in view of the Internet where the providers have no or limited responsibility towards EU citizens. The Pharmaceutical Forum was invited by the Directorate-General Enterprise & Industry of the EC to develop a strategy to identify the possible mechanisms to increase the level of access to information.

2. Proposal from the DG Enterprise and Industry

The objective pursued by the DG Enterprise and Industry seems related to the activities done so far by the Pharmaceutical Forum. DG Enterprise and Industry aims, in fact, at organizing a platform to bring together all relevant stakeholders – health professionals, patients, industry and regulatory authorities – to explore ways to increase the level of access to information.

As far as concerns this point, a public consultation promoted by the Directorate-General Enterprise & Industry is ongoing. It is directed to all stakeholders and interested parties on the key ideas for a cooperative legal proposal by the EC. The proposal would amend Directive 2001/83/EC. Though, the proposal should put the interest of patients first, and healthcare professionals should remain the primary source of health information, it would set rules on the provision of the information by marketing authorisation holders.

Therefore, the main objectives pursued are:

1. establishing a framework which provides EU citizens with understandable, non-promotional, high quality drug information;
2. maintaining the ban on direct-to-consumer advertising of prescription medicines, making sure that there is a clear distinction between advertising and non-promotional information;
3. avoiding unnecessary bureaucracy.

A fundamental objective of the legal proposal should be to provide rules that harmonise practices on information provisions to patients and to present a clear distinction between advertising and information on prescription medicines. Basically, communication not covered by the definition of advertisement should be regarded as information.

Following the experience of the Pharmaceutical Forum, a European consultant committee should be implemented in order to define general guidelines on drug information directed to patients; national regulatory authorities should create mixed working groups with the objective of setting codes of conduct and programs of monitoring industry information activities. Thus, industry can provide information to patient, though controlled.

Several documents distributed within the Pharmaceutical Forum show the intent to share experiences and activities developed in each MS and to explore the possibility to define a better standard of drug information to patients and health professionals. Interviews and questionnaires were formulated to collect information on specific activities done by pharmacists and national authorities in all European countries.

3. General comments

Our experience is based on the daily revision of all promotional material (visuals, booklets, reprints, etc.) that pharmaceutical industry delivers to prescribers and pharmacists in Italy. An average of 20 advertising packages are submitted to AIFA every single day before they are distributed to health professionals involved in drug prescriptions by more than 24.000 pharmaceutical industry representatives . Promotional material for the launch of new drugs is also used during health professional meetings (congresses, symposiums, meetings, etc.) which amounted to 18.000 events in 2007.

Most of this promotional material contains relevant information on drugs efficacy and safety and it should help prescribers to better understand how to use new medicines and new therapies. However, from our perspective it is important to distinguish advertising from independent information.

It is difficult to separate evidence-based from promotional-based drug information. The system should resign itself to adopt procedures of vigilance, to make a distinction between these two activities (profit vs non-profit), and to identify the difference according the actors involved. This may result in an oversimplification of the scenario but, at the moment, there is no other approach able to avoid the ambiguity of the information to patients, with no clear distinction between conflicting aims: better information to patients versus promotion of the

use of new and innovative therapies. Furthermore, today there is no evidence showing that the involvement of pharmaceutical companies in drug information allows patients to access to a more objective, understandable, non-promotional, high quality drug information. On the other hand, there are publications showing that direct-to-consumer advertising is directly correlated to an increase of drug use by patients exposed to these promotional activities.
The new approach presented in the public consultation and the Pharmaceutical Forum does not take into account that it is difficult, or even impossible, to set procedures able to:

- say if a campaign promoted by a pharmaceutical industry is done according to objective and non-promotional criteria;
- monitor if the impact of any kind of drug information, including industry and direct-to-consumer information – but not direct–to-consumer advertising – influences drug use and consumption;
- identify the responsibilities of the different stakeholders involved in drug information;
- adopt a transparent and objective methodology at European and national level to evaluate drug information.

For these reasons, it seems more rational to maintain a clear distinction between promotional activities and non promotional drug information to patients and identify "who is doing what". This means to leave the pharmaceutical companies the possibility to promote their products among health professionals without ambiguity and misunderstanding, and to distinguish this activity from information to patients.
Recently, examples of the involvement of pharmaceutical industry in drug information may be seen with the *educational plans* (some of these are directed also to patients) resulting as commitments by the companies during the marketing authorisation procedures. According to our experience several of these activities are more compliant with promotional aims then with risk management plans.

Evidence-based medicine is grounded on global data but drug information has to be based on local practices. In fact, data on drug safety and efficacy may be generalized for all European citizens, but drug information have to take into account local needs in terms of different accessibility to the sources, education, public health priorities, health services. In this context, it would be important to share different experiences and not to pursue a common approach and a unique model of drug information to patients.

4. Specific criticism and remarks

Given the objectives pursued by your proposal, we wish to contribute to the discussion with specific comments and remarks.

- *Establishing a framework which provides EU citizens with understandable, non-promotional, high quality drug information.*

Contribution from all stakeholders and interest parties dealing with medicines or with the provision of information on medicinal products to citizens are welcome; this covers, for example, information providers, healthcare providers, regulatory authorities and the pharmaceutical industry. However, a co-authorship of all these contributions does not guarantee a more understandable and coherent drug information, since these stakeholders, financially and intellectually, pursue different interests. Moreover, it is not clear how stakeholders' responsibilities will be defined.

The main objective of the Directorate-General Enterprise & Industry should be to support industrial competitiveness. It means that industries primarily aims at widening their own products market, while the main objective of health authorities and patients associations should be to protect consumers' needs.

The private interests of the pharmaceutical industry cannot and should not override public interests and public health.

The Pharmaceutical Forum produced a document on diabetes as an experimental approach able to summarize all these points of view. This was not so successful according to several independent societies and associations which see no added value in pursuing the model information package on diabetes[6]. These associations fully support the EU ban on Direct-to consumer-advertising and have concern about the lack of transparency of the processes in the Forum. They recommend that the future work of the group aims to look at existing models of good practices already existing in the EU Member States. They are convinced that reinforcing collaboration among existing national bodies involved in issuing independent patient information already represents a high added value for all Member States, EU citizens and patients.

- *Maintaining the ban on direct-to-consumer advertising of prescription medicines, making sure that there is a clear distinction between advertising and non-promotional information*

Under the clear safeguard that all advertisement to the public is banned, it should be possible for the pharmaceutical industry to disseminate information on prescription-only medicines through TV and radio programmes, through printed material actively distributed, through information in printed media or through audiovisual and written material provided to patients by healthcare professionals. Therefore, if prescription medicine-related information could be provided also by the pharmaceutical companies, clear quality criteria should distinguish the information that is allowed from the information that is not allowed. The methodology and the criteria to make all this possible is still not clear.

Priority setting and criteria to judge information on medicines able to contain non-promotional information seem a very hard effort to pursue.

Finally, your proposal does not specify transparency procedures needed to regulate a public-private partnership.

- *Avoiding unnecessary bureaucracy*

Your proposal mentioned that in order to facilitate the monitoring of the information provided by industry, a control mechanism should be set up, so that the information providers inform national co-regulatory bodies – which should monitor the information contents - about their activities. Moreover, citizens may ask pharmaceutical companies questions and replies by industry should be monitored by the same national co-regulatory bodies. By setting up all this mechanism, it is not clear how unnecessary bureaucracy could be avoided.

In your opinion, a European consultant committee should be implemented in order to define general guidelines on drug information directed to patients; national co-regulatory authorities should create mixed working groups with the objective of setting codes of conduct and programs of monitoring industry information activities. By implementing this monitoring network (both at national level and European level), bureaucracy is increased and not avoided.

5. Pharmaceutical industry and information to patients

Can pharmaceutical industry have a role in providing unbiased information to doctors and patients?

- *Misleading advertising to doctors and patients*

Direct-to-consumer pharmaceutical advertisements have been widely criticized for how they present data on drug benefit and side effects. Drug benefit is rarely quantified, and when

quantitative data are provided, they are typically provided in a format that tens to exaggerate perceptions of the effect size[7-9]. Today only in USA and New Zealand pharmaceutical industry is allowed direct-to-consumer information of prescription medicines. Nevertheless, this decision is not supported by all the stakeholders involved. In New Zealand, for instance, general practitioners demanded the ban on this kind of information, because they believe that it very dangerous for doctors, patients and the economy. They are particularly upset by the misleading content of the advertisements and the commercial pressure this puts them under to prescribe advertised drugs, even when they are no better than the existing alternatives or are not suitable for the patient[2]. Unfortunately, partial and unbalanced misinformation, which is the hallmark of direct-to-consumer advertising, is designed to drive choice rather than inform[3].

- *Information not timely provided by pharmaceutical companies to regulatory authorities*

Merck's withdrawal of rofecoxib from the market in September 2004 and Pfizer's announcement, in December of the same year, of possible cardiac risks associated with high doses of celecoxib reignited long-simmering controversies regarding drug promotion, in part because both cyclooxygenase-2 inhibitors have been heavily marketed directly to consumers. Indeed, after discussion with the Food and Drug Administration (FDA), Pfizer suspended all direct-to-consumer advertising of celecoxib.

Although the information made public in these cases is probably incomplete, these events offer an opportunity to step back and consider the appropriate role of drug promotion in general and direct-to-consumer advertising of prescription drugs in particular.[10]

- *Conflict of interest*

Industry information is concentrated on few products, mainly on new and innovative drugs, which are more expensive and gain more commercial success, though they are often no better than the existing alternatives.[2]

Therefore, there is no evident reason to think that pharmaceutical industry may provide unbiased information to patients.

6. Proposal from the Italian regulatory authority

AIFA does not support the idea to involve pharmaceutical companies in information activities to patients.

According to our experience the quality and the access to drug information may be improved by different approaches. We try to list some of these points:

1. *increase of transparency*

The mandate of the Pharmaceutical Forum working group on information to patients is to identify a methodology useful to enhance the access to high quality information on medicines. According to this, the contribution of the pharmaceutical industry in a private public collaboration could be to increase, as much as patent protection makes possible, the amount of data available before and after marketing authorisation.

2. *to promote drug information evidence based*

The quality of drug information is determined by the quality of evidence behind all messages reported. Also for the information delivered to the patient we should encourage systematic reviews and methodologies that allow an objective analysis of the data presented.

3. *to share experience and networking*

A network among countries with similar needs of information may be useful to save efforts and to harmonize approaches on drug information. It still has to take into account differences between MS and to allow to adapt interventions at local level.

4. *to support independent information*

In Europe there are several experiences of drug information delivered to patients by non-profit subjects. This activity has no conflict of interest with promotional or political aims and it may be used as a source of information to help citizens in a genuine process of empowerment for a rational use of medicines.

5. *to promote the EU Public Health portal*

A concrete aim of interaction between health authorities and pharmaceutical industry could be to implement and to support (with unconditional grants) a new and independent source of information web based, able to collect accountable and updated data on safety, efficacy and availability (including pricing) of medicines around EU.

7. Conclusion

The solution proposed consists of a bureaucracy whose ambition is to solve the industry conflict of interest by defining self-regulation codes and by creating committees which bring together different stakeholders, perspectives and mandates. Though the ban on direct-to-

consumer advertising of prescription medicines is still guaranteed, an ambiguous procedure is carried out which may make even more difficult to identify responsibilities and differences between advertising and information. Authorizing the pharmaceutical industry to advertise prescription medicines directly to consumers, by attempting to disguise promotion as "information" in this process, is alarming.

There several approaches that may be useful for better information on drugs to patients that still have not been examined and where the private-public partnership may be important.

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