



Making Medicines Affordable

## POSITION PAPER ON PATIENT INFORMATION:

### Response to the European Commission Report on current practices with regard to the provision of information to patients on medicinal products

(JUNE 2007)

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#### 1. Better Information to patients

In order to be fully engaged in their health, patients need access to high quality information about diseases, treatments and prevention. Patients should be able to easily access information in their own language that is unbiased and of assured quality and independence. Patients should also have the opportunity to obtain a greater understanding of diseases and the various treatment options available.

Better information to patients should seek to remedy three key weaknesses in the current system:

- The first major problem facing patients in the EU is the multitude of unregulated information through multiple and often unclear sources, especially via the Internet. Moreover, this information is often available only in English and targeted at audiences in the United States.
- The second major problem is that whilst other regulated and high quality information exists even in local languages (eg, information on the websites of medicines agencies), it is often not very user-friendly, and knowledge of the existence of such information is not well published to patients.
- The third problem is the need to establish the definition of what constitutes good information, to implement certification or approval methods, and to provide tools and guidance to European citizens to ensure access to patient-oriented information.

In dealing with these issues, the needs of patients must remain paramount over the interests of industry, both originator and generics companies. Whilst industry may represent an additional source of information, it must first be assessed if information from industry is genuinely necessary beyond what is or could be provided by healthcare professionals. Any information provided by industry must be governed by strictly defined criteria to avoid product promotion.

The European Commission has undertaken several initiatives to evaluate the availability and quality of existing information to patients; a Working Group on Patient Information was issued within the Pharmaceutical Forum and a *Draft report on current practices with regard to the provision of information to patients on medicinal products* is open for public consultation until the end of June 2007.



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## 2. Pharmaceutical Forum Working Group on Patient Information

The objectives of the Working Group were defined in October 2005 at the beginning of the Pharmaceutical Forum:

- To improve quality of information accessible to European Patients;
- To propose a electronic information tool;
- To agree on a Public Private Partnership.

### Quality Principles

The quality principles for good information as defined by the Working Group of the Pharma Forum are supported by the EGA: objective and unbiased, patient-oriented, evidence-based, up-to-date, reliable, understandable, accessible, transparent, relevant and appropriate, consistent with statutory information.

The EGA emphasises that information on medicinal products<sup>i</sup> must comply with the approved registration documentation of products. Therefore companies should be allowed to publish the PILs, EPARs and SmPCs of their products on their websites (PULL principle: available for patients actively looking for information). This is already common practice in parts of the European Union, but its application differs from Member State to Member State.

### Electronic information tool

To address the three weaknesses outlined above, the EGA proposes a 3-layered approach:

- Firstly, the European Union should establish a comprehensive and detailed on-line European Directory on Diseases, Prevention and Medicines. This should be available free of charge in all languages of the EU, and hosted by the European Commission, the EMEA and the Heads of Medicines Agencies. Medicines should at all times be mentioned by their international non-proprietary names (INN). This directory should contain links to other certified websites.
- Secondly, all national medicines agencies in the EU should develop comprehensive and freely accessible information to patients on all products on their market, via the Internet and other sources. The information provided would include approved registration documents such as the patient leaflet itself, EPARs and SMPCs. In addition, each agency should provide information on generic medicines, highlighting the quality, safety and efficacy of generic medicines, similar to current procedures carried out by the FDA and certain EU agencies.
- Thirdly, pharmaceutical companies should be allowed to place the approved PILs, EPARs and SmPCs about their products on their website (PULL principle: available for patients actively looking for information). Any other form of information published by companies about their own individual medicines must be based strictly on the above approved documents, must be in line with the quality criteria agreed in the Pharmaceutical Forum, and must be pre-approved by the competent authorities (not

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<sup>i</sup> Throughout this document, “medicines” or “products” refer to prescription medicines, not to OTC products



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by a Self Regulating Body). The authorities should establish a fee system in order to finance the resources needed for carrying out this activity.

Pharmaceutical companies should not be allowed to publish information on their individual medicines via other sources than their own website. Direct Information from industry to patients on individual products via newspapers, magazines, TV, etc (PUSH principle) is currently forbidden and should remain forbidden in future due to the possibility of this being used as a form of individual product promotion and the possibility of undue influence over patients.

### 3. The Direct-to-patient Information Tool on Diabetes

The EGA recognises the efforts of the Working Group to establish an “information tool” on diabetes. The structure of the information tool is clear and accessible to the public. However, given the numerous reactions during the public consultation process<sup>ii</sup>, especially from stakeholders that are experienced in the area of diabetes treatment, it is clear that the content does not comply with the quality criteria.

For many diseases there is no consensus on treatment. Even where agreement exists, there are many inter-patient differences, requiring that all advice should be given very carefully in order not to create confusion or - even worse - to cause patients to interrupt treatment from uncertainty.

Before the Commission decides to issue information tools on diseases, it should be clarified:

- which methodology can guarantee that the information tool complies with the quality criteria;
- who decides for which diseases this tool should be set up;
- how this information will be disseminated;
- which experts will draw up the information tool. The pilot project on the diabetes tool clearly shows that the members of the Working Group do not have the expertise to draw up these information tools.

### 4. Draft Report on current practices for patient information

DG Enterprise and Industry has launched a public consultation on a *Draft report on current practices with regard to the provision of information to patients on medicinal products*<sup>iii</sup>, as required under Article 88a of Directive 2001/83/EC, as amended by Directive 2004/27/EC on the Community code relating to medicinal products for human use.

The report contains the following information:

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<sup>ii</sup> The results of the consultation process can be consulted at:  
[http://ec.europa.eu/health/ph\\_overview/other\\_policies/pharmaceutical/results\\_consultation\\_en.htm](http://ec.europa.eu/health/ph_overview/other_policies/pharmaceutical/results_consultation_en.htm)

<sup>iii</sup> The report is open for Public Consultation until end June 2007 at:  
[http://ec.europa.eu/enterprise/pharmaceuticals/pharmacos/docs/doc2007/2007\\_04/draft\\_infopatients2007\\_04.pdf](http://ec.europa.eu/enterprise/pharmaceuticals/pharmacos/docs/doc2007/2007_04/draft_infopatients2007_04.pdf)



- an overview of the European legal framework for Information to Patients. The revised pharmaceutical legislation (Regulation (EC) n° 726/2004 and Directive 2004/27/EC) does not open up the rules applying to advertising medicines. A number of transparency measures were introduced in order to provide better quality information to patients and to the European public in general.
- The EMEA and the national medicines agency are obliged to make the patient leaflet, the SmPC and the public assessment report accessible to patients in a manner that is understandable to the public.
- Some Member State authorities and the European Medicines Agency play an extensive role in providing information to patients on authorised medicinal products and also allow stakeholders to provide information, while other countries apply very restrictive rules<sup>iv</sup>.

However, the report does not offer an accurate overview of what industry currently provides. A great deal of information on diseases and medicinal products is already available from industry. A search on the Internet shows that in some countries pharmaceutical company websites provide information on medicinal products in line with the approved registration documents (as explained in section 2 of this document). Other countries do not allow this information. In most countries, company websites already inform patients on disease areas and treatment options. Additionally, patient organisations, often sponsored by pharmaceutical companies, disseminate information on diseases via brochures, magazines, radio or television. All these existing practices are allowed by national legislation derived from the same European Regulation.

The EGA concludes that there is no need to change the European legislation<sup>v</sup> on information to patients and on advertising, but highlights the need for clear implementation and enforcement in all Member States. The EGA reiterates its opinion that stakeholders should be allowed to publish on their website information about diseases and approved registration documents on medicines. National legislation should also clarify to what extent companies are allowed to inform patients on certain groups of medicines, like generic medicines or biotechnological medicines, as long as no information on indications is given.

## 5. Conclusion

- The EGA sees no need for expanding European legislation<sup>v</sup>, but rather a need for clarifying current legislation in the various Member States.
- The EGA proposes the establishment of a European Directory on diseases, prevention and medicinal products, in order to guarantee access to harmonised, good quality information for European citizens.
- The EGA supports the possibility of the pharmaceutical industry to provide patients, who are actively searching for information (PULL principle) via their website, with the approved registration documents for their own medicinal products.

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<sup>iv</sup> See Annex II of the report: a survey of EGA through National Generic Associations shows that data in annex II are incomplete and incorrect. EGA will provide the Commission with the results of the survey through the Public Consultation phase.

<sup>v</sup> Legislation on Information to Patients is covered by Directive 2004/27/EC and Regulation (EC) No 726/2004.



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- Any other form of information published by companies on their own individual medicines must be strictly based on the approved documents listed above, must be in line with the quality criteria agreed in the Pharmaceutical Forum, and must be pre-approved by the competent authorities. Authorities should establish a fee system in order to finance the resources needed to carry out this activity.
- Pharmaceutical companies should not be allowed to publish information on their individual medicines via sources other than their own website. Direct information from industry to patients on individual products via newspapers, magazines, TV (PUSH principle) is currently forbidden and should remain forbidden in future due to the possibility of this being used as a form of individual product promotion and the possibility of undue influence over patients.

The EGA is the official representative body of the European generic pharmaceutical and biosimilar medicines industry, which is at the forefront of providing high quality affordable medicines to millions of Europeans and stimulating competitiveness and innovation in the pharmaceutical sector. The EGA's membership consists of generic medicine companies and national associations, representing the industry in 34 European countries.