

***Response to the European Commission public  
consultation on a  
Legal Proposal on Information to Patients***

***Joint Position Paper  
of the European Social Insurance Platform  
and  
the Medicine Evaluation Committee (MEDEV)  
of the European Social Health Insurance Forum***

***Submitted 7 April 2008***

### **About the *European Social Insurance Platform (ESIP)***

The *European Social Insurance Platform (ESIP)* represents Europe's social insurers in fourteen EU Member States and Switzerland, active in the field of health insurance, pensions, family benefits, occupational safety and accident insurance and unemployment insurance. The aims of ESIP and its members are to preserve high-profile social security for Europe; to reinforce solidarity-based social insurance systems and to maintain European social protection quality. ESIP builds strategic alliances for developing common positions to influence the European decision-making process and is a consultation forum for the European institutions and other multinational bodies active in the field of social security.

### **About the *Medicine Evaluation Committee (MEDEV)***

The *Medicine Evaluation Committee (MEDEV)* was established in 1998 as a standing working group of the European Social Health Insurance Forum, which comprises 16 national liaison agencies, associations and institutions for social health insurance in the EU Member States and Switzerland. Today, MEDEV represents the drug experts and pharmacologists of the national social health insurance organisations and other competent bodies in 14 EU Member States. The principal purpose of MEDEV is to provide the national health insurance organisations and other competent bodies with timely analyses about drug related trends and innovations at both national and European level. Further, with the overall objective of providing a necessary counterweight to the pharmaceutical industry, especially at EU level, MEDEV aims to support the EU's activities in formulating drug policies by giving input from the point of view of the statutory health insurers' and other competent authorities. MEDEV can offer expert advice to all EU bodies from the earliest stage of the pharmaceutical decision-making process and help them analyse the possible impact of drug-related policies on national health schemes.

For more information please visit the ESIP website at: [www.esip.org](http://www.esip.org)

***Response to the European Commission public  
consultation on a  
Legal Proposal on Information to Patients***

***Joint Position Paper  
of the European Social Insurance Platform  
and the Medicine Evaluation Committee (MEDEV) of the  
European Social Health Insurance Forum***

***Submitted 7 April 2008***

**SUMMARY** ESIP and the Medicine Evaluation Committee (MEDEV) welcome the opportunity to respond to the Commission's legal proposal on information to patients. However, we deeply regret the process followed by the Commission in arriving at this proposal, which is clearly driven by the interests of industry and not those of the patient. The proposal goes far beyond the issues covered by the various public consultations on this subject and fails to take into consideration the responses made to these consultations and the issues raised in the continuing debate in the Pharmaceutical Forum. Further, the proposal neither meets the objectives set out in Article 88a of Directive 2001/83/EC, nor does it adequately address the issues of unequal access, quality of information or accountability.

**Background**

In 2002, as part the package of proposals establishing a European Regulatory Framework on medicinal products (adopted in 2004) the European Commission DG Enterprise and Industry proposed to lift the EU ban on advertising of prescription only medicines by industry as a "pilot project". This proposal was overwhelmingly rejected by the European Parliament in 2003. Instead the European Parliament called on the Commission to prepare **a report** by 2007 on *current practice with regard to information provision - particularly on the Internet - and its risks and benefits for patients* (Article 88a of Directive 2001/83/EC). Article 88a further provides that *following analysis of the above data, the Commission shall, if appropriate, put forward **proposals setting out an information strategy** to ensure good-quality, objective, reliable and non-promotional information on medicinal products and other treatments and shall address the question of the information source's liability.*

In April 2007, the Commission produced its draft report (essentially an inventory) on current practices with regard to information provision, which was subject to a public consultation. The

final report published in December 2007 concluded that rules and practices on information on medicines differ between the Member States (MS) resulting in **unequal access to information** by citizens across the EU. It further concluded that the **quality of information is very variable**, in particular with view to the Internet where providers have **no or limited accountability** to EU citizens.

Reputedly on the basis of the final report, the Commission began an **impact assessment** study collecting opinions and data (between December 2007 and February 2008) on the likely impacts of the **main options for legal proposals** that would allow **industry** to provide information on their medicines directly to the public.

Then on 5 February 2008, while the impact assessment was still in progress, the legal proposal on information to patients which is the subject of the current public consultation was launched. This proposal sets out the key ideas for a forthcoming **legal proposal that would amend Directive 2001/83/EC and set rules on the provision of information by marketing authorisation holders**.

In parallel to this legal process, the European Commission established the **Pharmaceutical Forum** working group on information to patients in 2005. The overall aims of the Forum being to improve the competitiveness of Europe's pharmaceutical industry while enhancing patient's access to medicines. ESIP, along with representatives of the MS, the Commission, European Parliament and other stakeholders, including industry has actively contributed to the very extensive work and debate undertaken by this working group which will reach its final conclusions in October 2008.

## **1. ESIP and MEDEV standpoint**

In 2003, ESIP and MEDEV advocated maintaining the ban on direct to consumer advertising (DTCA) of prescription only medicines, a view which we continue to advocate today (1). In the on-going debate in the Pharmaceutical Forum on the possible role of industry in the provision of information to patients, in our responses to the numerous public consultations on this subject in 2007 (2,3,4) and through our members' contributions to the impact assessment we have expressed our very grave concerns about the risks involved in weakening this ban and allowing the pharmaceutical industry the possibility to communicate directly with the patient under the guise of providing "information" on its products (or on diseases).

We are further concerned by the process followed by the Commission in arriving at the current legal proposal, which is clearly driven by the interests of industry and not those of the patient. The proposal goes far beyond the issues that have been covered by the various public consultations and the continuing debate in the Pharmaceutical Forum by introducing the idea of "pushed" information, including medicine related information not covered by the approved SPCs and PILs, via the full range of media including TV, radio, audiovisual and written materials. In addition, the proposal neither meets the objectives set out in Article 88a of Directive 2001/83/EC, nor does it adequately address the issues of unequal access, quality of information or accountability.

## **2. Comments to the Commissions proposals under consultation**

### **a Maintaining the prohibition on DTCA of prescription only medicines**

Although the current proposal claims that the current ban on advertising of prescription only medicines will be maintained it opens the door to widespread abuse of what is already a very

---

unclear distinction between what is information and what is advertising by allowing industry to “*push*” information to patients. This information will not be limited to information that is consistent with approved SPCs and PILs and not going beyond the key elements on them (as defined by the quality criteria adopted by the Pharmaceutical Forum) but will be extended to include medicine-related information such as information on scientific studies, prevention of disease, accompanying measures and prices. The pharmaceutical industry will be free to disseminate this information through TV and radio programmes, printed material actively distributed, information in printed media and audiovisual and printed material provided to patients by healthcare professionals. This information will be provided on a “tell and do” basis and will not be subject validation prior to dissemination (*ex-ante*). This is totally unacceptable. Furthermore, the sheer quantity of information will be impossible to monitor (*ex-post*). ESIP and MEDEV strongly oppose such a change to the legislation.

### **b Pharmaceutical industry as a source of non promotional information**

The pharmaceutical industry already has an obligation to provide key information about the risks and benefits of its medicines to the regulatory authorities (and health professionals). This information should be available to the public through the approved patient information leaflet (PIL), the assessment reports and the summary of product characteristics (SPC) which should be regularly updated and accessible via Internet on the website of the European Medicines Agency (where this is already the case) and on the websites of the Member States’ health authorities. Ensuring complete transparency and universal access to this information should be the primary goal of an EU information strategy on medicines.

The Commission proposal would allow industry to provide information directly to the public which is compatible with the approved information (SPCs and PILs) as well as a range of other medicine related information. The assumption is that allowing industry to provide this information would reduce inequalities in access to good-quality objective, reliable and non-promotional information on medicinal products. The Commission puts forward no evidence to support this assumption in its proposal.

In the real world, it would be difficult to see what motivation industry had to provide information if it wasn’t to promote its products. In the competitive pharmaceuticals market, companies are driven to champion their own medicines; conflict of interest therefore prevents them from providing the comparative yet unbiased information that patients need to make an informed decision about their medication. The proposal strictly rules out the inclusion of comparative information between products (6. Table) - a safeguard that ESIP and MEDEV fully support.

Further, while being objective, the pharmaceutical industry can be selective about which products it provides information on. These products are likely to be the blockbusters and not the most cost-effective medicines, which is not in the interest of the patient, the general public or the healthcare systems. Evidence from countries where DTCA is allowed (New Zealand and the USA) shows that publicity creates patient demand, leading to over subscribing by doctors, increases in non-justified health spending and increased exposure of patients to adverse effects (5).

Finally, the proposal envisages the provision of information by industry directly to patients about scientific studies. The serious danger with this proposal is that this could stimulate demand for the premature commercial launch of drugs on the basis of very limited information about its efficacy and safety. Linked with the recent Commission proposal on pharmacovigilance, which aims to speed up the marketing authorisation process by generalizing “conditional” and “exceptional” authorisation procedures this proposal poses a serious risk to patient safety.

### **c Distinction between information and advertising**

A fundamental objective of this proposal is said to be “making sure that there is a clear distinction between advertising and non-promotional information” (paragraph 2.2.2). For this purpose it refers to the definition of advertising under Article 86 of Directive 2001/83/EC and use of the Quality Criteria on information which were developed and adopted by the Pharmaceutical Forum in 2006 (paragraph 4), which ESIP and MEDEV welcome. However, paragraph 3.2 states that “Communication not covered by the definition of advertising should be regarded as information”. On the contrary, anything that doesn’t comply with the quality criteria should be considered advertising; if not, compliance with the quality criteria would be meaningless. Further, under the definition of the quality criteria (6. Table), a new criterion “non-promotional” has been added with the definition that information should “*focus on* informing and guiding patients to correct and safe use of the medicine”. This weak definition leaves the field open to promotional presentations of products within the context of correct and safe use.

Despite the use of the quality criteria it will be very difficult for the competent authority/body and in particular the patient to distinguish between information and advertising. For this reason, ESIP and MEDEV have advocated the evaluation of information on the basis of the established quality criteria prior to its dissemination i.e. ex-ante and the subsequent clear labelling of quality approved information (2,3,4).

### **d Weaknesses of the proposed co-regulatory system and sanctions**

The proposal set out here does not envisage a system of scientific assessment or validation of the information either ex-ante or ex-post. Industry is only obliged to ‘*inform*’ or “*announce*” its activities to the National Co-Regulatory Body before carrying them out in order to facilitate the monitoring of those activities ex-post. As noted above, this is totally unsatisfactory.

Further, in cases of breach of the code of conduct (to be adopted by the co-regulatory body) the Commission envisages only a very weak system of sanctions. The first level of sanctions is public embarrassment – *name and shame*, and only in cases of ‘repeated and severe cases of non-compliance’ would referral be made to national competent authorities who could apply penalties (which are undefined). The weakness of the system is further compounded by the fact that the pharmaceutical industry should form part of the national co-regulatory body such that industry representatives would determine the initial disciplinary measures against its own members.

The co-regulatory system described in the Commission proposal relies heavily on the willingness of the industry to exercise self restraint. However, experience shows that this is not always the case (6), in particular as the benefits from dissemination of promotional information via the mass media are likely to be far greater than the threat of public embarrassment further down the line.

Notwithstanding the weaknesses of the system as outlined above the proposed structure for monitoring information would require massively increased resources in the MS.

## **3. Tackling inequalities in access to quality information**

The basis of the Commission’s proposal is reported to be the need to address the inequalities in access to information on medicines between the Member States, to ensure the high quality of that information and establish a system of accountability by the provider. At the same time, the proposal should put the interests of patients first, maintain the confidence

of citizens, regulators and healthcare professionals and avoid unnecessary bureaucracy. The proposal fails to do any of these things because it envisages only one solution and that is the provision of information by industry.

The variation in rules and practices between Member States is a reflection of legitimately different national approaches to the issue of providing information to their citizens. It is the Member States who are responsible for the management and financing of their health systems and who are therefore in a better position to make judgments about how information is disseminated.

Throughout the Member States there are many good examples of good practice with regards to the provision of independent, evidence-based information on medicines (7). Indeed a number of organisations and institutes responsible for the provision of information at a national level have already established an international reputation e.g. the Institute for Quality and Efficiency in Health Care (IQWiG) in Germany. The Commission's proposal as it stands would undermine these activities and lead to poorer quality information and increased uncertainty for the patient. Therefore, any future information strategy at EU level should rather support the production of information by independent bodies and focus on establishing a network of collaboration between Member States to facilitate the exchange of information and good practice. Further the adoption of an EU quality label to identify independent, high quality, approved information could provide a real benefit for the patient.

## **References**

- 1 Position of the European Social Health Insurance Forum on the Council Common Position towards adopting: a Regulation of the European Parliament and of the Council laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (EMEA) (10949/03 – 2001/0252(COD)) and a Directive of the European Parliament and of the Council amending Directive 2001/83/EC on the Community code relating to medicinal products for human use (10950/03 – 2001/0253(COD)), submitted to the European Parliament, November 2003.
- 2 AIM and ESIP joint position on Pharmaceutical Forum priority topics, 29 September 2006 (<http://www.esip.org/publications/pb91.pdf>)
- 3 ESIP joint comments on Public Consultation on Patient information Joint Position Paper of the European Social Insurance Platform submitted 04 May 2007 (<http://www.esip.org/publications/pb126.pdf>)
- 4 ESIP joint comments on the public consultation on the "Draft report on current practice with regards to provision of information to patients on medicinal products" submitted to the European Commission DG ENTR on 29 June 2007 (<http://www.esip.org/publications/pb127.pdf>)
- 5 Jonathan M Metzl MD: If direct-to-consumer advertisements come to Europe: lessons from the USA. The Lancet 2007; 369:704-706
- 6 The Influence of the Pharmaceutical Industry: report of the House of Commons 2005, paragraph 227.
- 7 Joint Declaration of HAI Europe, ISDB, BEUC, AIM and the Medicines in Europe Forum "Relevant Health Information for Empowered Citizens", 03 October 2006 (<http://www.prescrire.org/cahiers/dossierEuropeMedInfoPatientAccueilEn.php>)

This position paper has the support of the member organisations of ESIP<sup>1</sup> and MEDEV in so far as the matter lies within their field of competence.

---

<sup>1</sup> *ESIP members support this position with the specific exception of the International Pension Centre, the Försäkringskassan and the Sociálna poisťovňa since the subject matter covered by this paper falls outside their field of competence.*