

**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”***

*In accordance with Article 88a of Directive 2001/81/EC,
as amended by Directive 2004/27/EC*

***Joint Position Paper
of the European Social Insurance Platform***

submitted on 29 June 2007

About the *European Social Insurance Platform (ESIP)*

The *European Social Insurance Platform (ESIP)* represents the social insurers of over thirty organisations from fourteen 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.

For more information please visit the ESIP website at: www.esip.org

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Joint Position Paper

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submitted on 29 June 2007

- **ESIP calls for retaining a strict ban on direct to consumer advertising (DTCA).**
- **ESIP urges the European Institutions to keep Article 88, paragraphs 1 and 3 of Directive 2001//81/EC as amended by 2004/27/EC unchanged.**
- **ESIP calls on the Commission and the Member States to improve awareness and access to existing sources of high-quality, evidence-based and patient-centered information.**
- **ESIP encourages the Commission and the Member States to establish a network of competent authorities to exchange good practices and existing information.**
- **ESIP supports the idea of a quality label for good information to patients and,**
- **ESIP asks the Commission to make a feasibility study for its implementation.**

I. Background

With the draft report - which is the basis of the current consultation - the Commission aims to fulfil their legal obligation laid out in Article 88a of the Directive 2004/27/EC¹

¹ Article 88a, Directive 2004/27/EC (OJ 2004 L136/34)

Within three years of the entry into force of *Directive 2004/726/EC*, the Commission shall, following consultations with patients' and consumers' organisations, **doctors' and pharmacists' organisations**, Member States and other interested parties, present to the European Parliament and the Council a report on current practice with regard to information provision - particularly on the Internet - and its risks and benefits for patients.

to prepare a report on “current practice with regard to information provision – particularly on the Internet – and its **risks** and benefits for patients.”

In preparing the draft report the Commission was obliged to consult patients’ and consumers’ organisations as well as doctors’ and pharmacists’ organisations, Member States and other interested parties.

What is DTCA?

DTCA is the advertising of prescription-only medicines or treatments to consumers.

DTCA specifically advertises individual branded medicines for a specific condition.

DTCA refers to:

- promotional material transmitted via television, radio, posters, magazines and the Internet
- a range of ‘patient education promotion activities’ (such as disease-oriented advertisements, toll-free numbers, information materials distributed by company-funded organisations, media reports generated by company-sponsored press conferences, and public meetings).²

Currently direct-to-consumer advertising (DTCA) is forbidden in the EU.

II. General remarks on the draft report

The current Draft Report on “current practice with regards to provision of information to patients on medicinal products” is a good example of how exactly information to the public should **not** be provided. The Draft Report is of poor quality; it fails to meet several of the core quality principles³ for information set out by the working group on patient information of the Pharmaceutical Forum. The report even incorrectly quotes Article 88a by leaving out its obligation to consult doctors’ and pharmacists’ organisations.

The Draft Report **lacks transparency**. It makes poor reference to the methodology used to make the assessment and almost none to the sources of information that form the basis of the conclusions. The Draft Report provides no satisfying evidence that the Commission has met its obligation to consult with “*patients’ and consumers’ organisations, doctors’ and pharmacists’ organisations, Member States and other interested parties.*”

The Draft Report **lacks accessibility**. The report and the *public* consultation are not easy to find on the Commission’s web site: they are not available on the Commission’s own dedicated *consultation* website – *Your voice in Europe* – nor on that of DG SANCO. Further, the report is only available to English speaking persons.

Article 88a, Directive 2004/27/EC continued from page 3:

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.”

2 Ministry of Health, New Zealand:

<http://www.moh.govt.nz/moh.nsf/238fd5fb4fd051844c256669006aed57/59fe3fe79c8f9758cc257125006ea9a2?OpenDocument#1>

3 Pharmaceutical Forum Working Group on Information to Patients Core principles for patient information on diseases and treatment options, version released for public consultation in April 2007:

http://ec.europa.eu/health/ph_overview/other_policies/pharmaceutical/docs/quality_principles_en.pdf

The report therefore excludes the vast majority of stakeholders active locally in the field of providing information to patients. Therefore the outcome of this public consultation will have a strong systematic bias making it of questionable value. A fully open public consultation would be desirable.

The Draft Report **is not unbiased, neutral or balanced**. It only briefly lists some of the current practices in the Member States. The report fails to mention existing or possible solutions to meeting patients' needs for more quality information.

The Draft Report overemphasises the benefits of more information, in particular information provided by the pharmaceutical industry, and fails to fulfil its obligation to examine the risks of information. The Draft wrongly concludes in paragraph 2 of point 4.5 that more information through Community legislation will solve the problem of unequal access based on technological skills, language and age. The current EU legislative framework does not hamper equal access to information.

The Draft report also wrongly concludes in paragraph 3 of point 4.5 that more information (from industry) will solve the problem of illegally advertised and sold counterfeit medicines. More information only veils the problem and makes the distinction between legal and illegal advertising more problematic. These issues should be dealt with by the competent authorities of Member States and of the European Union.

In the conclusions of the Draft Report the Commission states that under the current legislative framework the "...the pharmaceutical industry possesses the key information on their medicines but this information can currently not be made available to patients and healthcare professionals ...". The Commission fails in the Draft Report to indicate the nature of this *key* information – *other than the advertising of prescription only drugs* - and why this information could not be made available in a reader friendly, consumer / patient orientated leaflet within the current legal framework. Indeed, it should be mentioned that the Medicine Agencies (EMA and national authorities) already possess additional "key information" that they currently do not make available. These authorities should be responsible for making this information available to patients in an objective, unbiased and patient centred way.

The Draft report itself points out correctly that "A profound assessment on the perception of the different practices (*regarding the provision of information to patients: add. by the author*) in Member States is not available." Unfortunately the Commission does not bridge that gap with this Draft Report and therefore falls short of its aim to "... report on current practice with regard to information provision - particularly on the Internet - and its risks and benefit for patients" (Article 88a).

III. ESIP's suggestions for improving information to patients on medicinal products

ESIP calls up the Commission to carry out a comprehensive study on the provision of information to patients which clearly identifies the *needs* of patients. The study should focus on the unmet needs and missing information as well as pinpoint where information is available but not distributed properly throughout the EU and its citizens. The study should also focus on currently hidden information on the adverse side effects of medicinal products and failed pharmacological studies and propose ways to make this information more easily accessible. Finally, the study should aim

to identify existing examples of high-quality information to patients and propose ways to increase awareness of this information and its sources.

ESIP encourages the Commission to set up a network of competent authorities and other bodies in the Member States involved in the provision of information to patients. This would facilitate the distribution of information and avoid the duplication of work.

ESIP asks the Commission to undertake a feasibility study for setting up a national or European label for good quality information. The label should be awarded to information which has been produced under agreed standards of good information practice as set out by the Pharmaceutical Forum working group on information to patients.

ESIP strongly believes that there is no lack of information under the current legislative framework. The gap is in providing this information in the right language, at the right time, in the right place and in a receiver tailored way. Investigating existing examples of good practice⁴ could provide the basis for bridging that gap.

Therefore Article 88 Paragraph 1 and 3 must remain unchanged.

Summary

ESIP calls for:

- **A strict ban on direct to consumer advertising (DTCA)**
- **The European Institutions to keep Article 88 of Directive 2001//81/EC unchanged**
- **The Commission and Member States to improve awareness and access to existing sources of high-quality, evidence-based and patient-centered information**
- **The Commission and Member States to establish a network of competent authorities to exchange good practices and existing information**
- **A quality label for good information**

⁴ For example, provision of information by national bodies such as: NICE (UK), IQWIK (DE), HAS (FR)

This position paper has the support of the following organisations as far as their competences are touched:

AUSTRIA	HVSVT	Hauptverband der österreichischen Sozialversicherungsträger, Vienna
BELGIUM	ONP/RVP	Office National des Pensions/Rijksdienst voor Pensioenen, Brussels
CZECH REPUBLIC	CSSZ	Czech Social Security Administration, Prague
FINLAND	ETK	The Central Pension Security Institute of Finland, Helsinki
	FAIL	Federation of Accident Insurance Institutions, Helsinki
	TVR	Finish Unemployment Insurance Fund, Helsinki
FRANCE	FNMF	Fédération Nationale de la Mutualité Française, Paris
	CNAF	Caisse Nationale d'Allocations Familiales, Paris
	CNAM	Caisse Nationale d'Assurance Maladie, Paris
	CNAV	Caisse Nationale d'Assurance Vieillesse, Paris
	CCMSA	Caisse Centrale de la Mutualité Sociale Agricole, Paris
GERMANY	AOK-BV	AOK-Bundesverband, Bonn
	BKK-BV	Bundesverband der Betriebskrankenkassen, Essen
	IKK-BV	Bundesverband der Innungskrankenkassen, Bergisch Gladbach
	LKK-BV	Bundesverband der landwirtschaftlichen Krankenkassen, Kassel
	VdAK	Verband der Angestellten-Krankenkassen, Siegburg
	AEV	Arbeiter-Ersatzkassen-Verband, Siegburg
	Kn	Knappschaft, Bochum
	See-KK	See-Krankenkasse, Hamburg
	DGUV (HVBG/BUK)	Deutsche gesetzliche Unfallversicherung, Berlin
	BLB	Bundesverband der landwirtschaftlichen Berufsgenossenschaften, Kassel
	DRV	Deutsche Rentenversicherung Bund, Berlin
	GLA	Gesamtverband der landwirtschaftlichen Alterskassen, Kassel
ITALY	INPDAP	Istituto Nazionale di Previdenza per i Dipendenti Dell'Amministrazione, Rome
	INPS	Istituto Nazionale della Previdenza Sociale, Rome
LUXEMBOURG	ALOSS	Association Luxembourgeoise des Organismes de Securite Sociale, Luxembourg
THE NETHERLANDS	SVB	Sociale Verzekeringsbank, Amstelveen
	CVZ	College voor Zorgverzekeringen, Amstelveen
POLAND	ZUS	The Social Insurance Institution of Poland, Warsaw
ROMANIA	CNAS	Casa Națională De Asigurări De Sănătate, Bucharest
SWEDEN	FK	Försäkringskassan, Stockholm
SWITZERLAND	SUVA	Schweizerische Unfallversicherungsanstalt, Lucerne