

***ESIP joint comments on
Public Consultation on Patient information***

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

***submitted
04 May 2007***

About the *European Social Insurance Platform* (ESIP)

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

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ESIP represents the social insurance organisations in 14 EU Member States and Switzerland. Our organisations provide coverage against sickness and other social welfare risks to around 300 million people, either by participating directly in the management of compulsory health insurance, by providing voluntary health insurance or by delivering directly health care and social services through own facilities. Social health insurance organizations are not just payer organizations; they are at the same time spokespersons for their 300 million insured members/patients. Based on not-for-profit principles, our member organisations have a duty to their insured persons to allocate their limited financial means to the most effective and cost efficient drugs at the most competitive prices. ESIP claims value for money in the interest of its members.

General comments on the consultation

ESIP is participating as full member in the Pharmaceutical Forum including in the patient information working group. As the opinions of the representatives in the Pharmaceutical Forum Patient information working group are **divergent on crucial aspects**, ESIP considers it important to reaffirm its respective position through the public consultation initiative.

Goal: steps towards an informed and empowered patient

Today's information society provides a vast amount of health related information via a multitude of sources and channels. In order to manage this information, there is a **real need to provide tools and guidance to citizens and patients so that they can identify objective, evidence-based and unbiased information, independent**

from commercial interests. In addition to Member State national bodies¹ responsible for issuing patient information many other sources of independent high quality information already exist. Improving awareness of these existing sources would constitute an added value for citizens. **To boost the access of citizens to patient-centred evidence-based, independent and evaluated information ESIP calls for a specific EU-logo² as trust mark** for the citizens to identify accredited, independent information.

Direct-to-consumer advertising (DTCA) for prescription drugs is forbidden in the EU. ESIP fully supports the ban on DTCA which was clearly reaffirmed by the European Parliament and the Council of Ministers in 2004. Weakening the ban on DTCA would open the door to a wave of marketing that will be difficult to control following international experience³. The result of this would be to create unnecessary demands which are not in the interest of public health and does not provide a better health status for patients.

In the interest of the patients and citizens, **ESIP strongly demands that public health interests are not mixed or even replaced with commercial interests.**

Quality principles

The main problem in the discussions in the working group focused on the inclusion of the criterion “unbiased” information.

ESIP insists that “unbiased” is included in the list of criteria since it is crucial to guarantee that information is free from commercial interests. “Unbiased” is more encompassing than “objective”. Unbiased not only refers to the source of information; it also means that all available information (including positive and negative results of trials, for example) has to be taken into account (to provide suitably high quality information. The wording of patient information should also be unbiased).

ESIP would also highlight the importance of “validated” information. As the source of information may lead to conflicts of interest (commercial) the principle of an independent assessment by a recognised scientific and impartial body should therefore also be added to the list of criteria.

ESIP changes to the list of criteria are indicated below in italic.

NEW Assessment and validation

In order to guarantee to the general public that the quality criteria have been respected, patient information needs to be assessed and validated by a public health authority or by an independent body established by this authority. Approved and validated information should be easily identified by a common EU quality mark.

¹ NICE, IQWiQ, HAS, etc.

² Such a logo would need to be designed.

³ Editorial in the lancet, Vol 369, January 6, 2007

NEW *Unbiased*

To make informed choices, people need correct, unbiased (complete, balanced, objective) and comparative information. The source of information should always be made clear. Public authorities should make unbiased sources of patient information known to the citizens.

Evidence-based

The evidence base for any information resource needs to be clearly stated, including making clear when evidence does not exist. Information should be verifiable, based on *validated* comparisons and backed up by scientific peer review where possible.

Up-to-date

Information should be kept up-to-date and the date of publication should be included.

Reliable

Information needs to be factually correct and not misleading. Information should be scientifically valid and reflect latest knowledge.

Understandable

Information provided should be comprehensible for the patient/citizen.

Accessible

Information should be easily accessible via different mechanisms (written documents, websites of certified official bodies). Information should also be accessible to people with disabilities.

Transparent

Informed choice requires transparency. That entails transparency of what is known as well as what is not known. Funding, sources of information, evidence for that source and transparency when there is known controversy about a particular treatment, for example, all need to be made clear. *Information needs to be referenced and the author and his organisation should also be indicated.*

Relevant and appropriate

Information should include issues of relevance and importance to patients' decision-making e.g. including adverse effects. Impact on quality of life and the consequences of the disease on contribution of the patient to society/the work place are important elements of information on disease.

NEW *Consistent with Statutory Information*

Information not regulated by statute must comply with the legal requirements of European law. The ban on DTCA should continue to be the leading principle governing patient information.

The draft “Direct-to-patient information tool on: “Diabetes”

ESIP has some important concerns regarding the drafting procedure as well as the factual content of the proposed diabetes factsheet.

- **Intransparency of methodology and quality criteria:**
First and foremost, it is to be regretted that this document has been drafted without any agreed methodology and procedure. Furthermore, the draft does not comply with the quality criteria discussed above (it is not evidence-based, up-to-date, understandable, transparent). The paper does not mention the authors. In addition cited references should be linked via footnotes to the specific point rather than being simply listed.
- **Comprehensibility:**
The paper is written in a rather complicated style only comprehensible to patients and persons with intermediate or higher education – even with clarification of the medical terms. In order to reach less well educated people – who are in fact at higher risk of getting diabetes – the paper has to be shortened and the style of writing has to be more colloquial. Also the comprehensibility could be improved by using pictures or pictograms to illustrate the text.
- **Omissions and mistakes:**
The symptoms of type 1 and type 2 diabetes are insufficiently described, especially as regards hypoglycaemia. . The management – “global partnership for effective diabetes management”- of these two diseases is insufficiently highlighted. Controversial aspects e.g. as regards the effectiveness of some treatments are not mentioned.
It may be helpful to indicate which treatment option is the usual “standard” and which treatments are only recommended under certain circumstances.
Also likely harmful and adverse side effects should be mentioned alongside the treatment options. No comparative information is provided that might allow shared, informed participation in treatment choice.
Annex 1 contains further remarks on the scientific content of the factsheet.

In general, ESIP has serious concerns about the added value of such factsheets. Even if adjusted to include all of our above comments, on its own it does not improve the level of information already well known and publicly available to patients.

The current consultation does not raise the issue of how information to patients will/should be developed, assessed and disseminated and who will be responsible for this in the future. ESIP believes that these outstanding issues are crucial and can not be separated from the draft proposal. We believe that this is the responsibility of competent authorities at Community and national level.

ESIP is convinced that increasing awareness of and accessibility to existing sources of high quality information would represent a real added value to citizens and patients. Exchange and collaboration among Member States national bodies should also be encouraged.

Annex 1:

Scientific remarks to the factsheet on patient to information

- The definition of diabetes mellitus in Germany differs from the definition in the draft (before a meal in the morning: 3.9 – 6.1 mmol/l; two hours after meals less than 11.1 mmol/l). A lot of medical institutions and patients also use the unit “mg/dl”.
- Despite the fact, that most EU-countries are alcohol permissive societies, patient information should contain more serious hints about the harmfulness of alcohol, especially for diabetes patients. The formulation “ensuring alcohol intake is moderate” is not suitable.
- For a lot of people with diabetes mellitus type 2 it is too little to propose one glucose check by the physician every 3 - 6 months.
- To refer to HDL-Cholesterin is not sufficient. The patient information should also refer to total and LDL-cholesterol.
- Referring to “Hands and feet” it would be helpful to mention the pain often suffered in these cases to underline the need for regular and careful manicure / pedicure.
- Weight loss and muscle wasting are primarily symptoms of diabetes type 1.
- Often the first check for diabetes is a blood-test and not a urine sample. The glucose tolerance test in some Member State is with blood samples every hour (not every half hour) for two hours. In addition in the most recent guidelines, urine glucose analysis is not recommended as a screening test and the oral glucose tolerance test is not recommended for diagnosis.
- More information is needed about hypoglycaemia, its dangers and emergency therapy as well as about the associated complications and their therapy.
- In some Member States, it is not usual or general to supplement metformin treatment with sulphonylurea or glitazone, when metformin alone proves not to be sufficient. It depends on the individual situation, what kind of therapy would be chosen as the next step.
- Combining medical drugs is often not recommended
- When sufficiently treated, diabetes itself is no reason for restrictions concerning work or specific jobs. Diabetes does not commonly lead to general invalidity. The mentioned aspect of “information about obtaining and renewal of a driver’s licence” may also be misunderstood.

This position paper has the support of the following organisations in so far as the matter lies within their field of competence:

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
	FAII	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
	HVBG	Hauptverband der gewerblichen Berufsgenossenschaften, Sankt Augustin
	BLK	Bundesverband der landwirtschaftlichen Berufsgenossenschaften, Kassel
	BUK	Bundesverband der Unfallkassen, Munich
	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
SWITZERLAND	SUVA	Schweizerische Unfallversicherungsanstalt, Lucerne