

***Information to the general public on medicinal  
products subject to medical prescription***

***Proposal for a directive amending Directive 2001/83/EC  
COM(2008) 663 final***

***Proposal for a regulation amending Regulation (EC) No 726/2004 COM(2008)662  
final***

***Joint Position Paper***

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

***Submitted 20 March 2009***

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

The *European Social Insurance Platform (ESIP)* represents Europe's social insurers in 16 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, comprising 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 about ESIP or MEDEV please visit the ESIP website at:  
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# ***Information to the general public on medicinal products subject to medical prescription***

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## **Background**

In 2001, as part of 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** 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).

The final report published by the Commission in December 2007 concluded that rules and practices on information on medicines differ between the Member States resulting in **unequal access to information** by citizens across the EU. This conclusion is not fundamentally wrong but the interpretation by the Commission is questionable. Reputedly on the basis of this 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. On 5 February 2008, while the impact assessment was still in progress, a legal proposal on information to patients which was the subject of a public consultation was submitted. This proposal set 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**. Between February and early April 2008 this proposal was subject to another public consultation. Once again, the wider public health community has unanimously stated, that the pharmaceutical industry cannot be considered as a reliable source of unbiased information, due to an obvious and unavoidable conflict of interest.

**Despite this opposition, in clear contradiction of the message expressed by the European Parliament in 2003 and also dismissing objections from a number of Commissioners, a legal proposal to amend the Directive was finally adopted on 10 December 2008 by the European Commission, as part of the so called “pharmaceutical package”.**

## **Summary**

**The proposal can not be supported by ESIP and MEDEV because it:**

- **puts forward no evidence that industry possesses** additional **useful** information that is not already available to the patient,
- does **not establish clear-cut distinction between advertising and information,**
- **allows** industry to **“push” information** to patients,
- does **not tackle inequalities** in access to **quality** information,
- does **not guaranty the quality** of information,
- offers possibilities for provision of **selective information,**
- **creates an enormous bureaucratic and expensive regulatory system** which nevertheless cannot be effective,
- does **not guarantee** systematic ex-ante **control,**
- sets rules for the **registration of websites** which will result in quality standards of the **lowest common denominator.**

Moreover ESIP and MEDEV regret that the European Commission has not adequately taken into account the opposing opinions and comments expressed in the several consultations held over the last years and also in the Pharmaceutical Forum.

ESIP and MEDEV call for Commission action to support the dissemination of information by independent bodies and focus on efforts to establish a network of collaboration between Member States to facilitate the exchange and dissemination of high quality information and good practice.

**ESIP and MEDEV would like to call upon all Members of the European Parliament to act once again in the interest of the European patients** and not in the interest of the pharmaceutical industry. It is consequently the role of the Parliament to fully play its role as co-legislator and the voice of EU citizens, by **rejecting the proposal.**

Instead of making suggestions for improved provision of high quality patient information and increased cooperation among the Member States, **the proposal opens up possibilities for the pharmaceutical industry to promote its products to the general public. Hence, the proposal must be considered a means to open up alternative and new ways of direct to consumer advertising (DCTA).** In addition, information provision by the industry is not confined to participation in public private partnerships but will be possible directly by the pharmaceutical industry itself.

Healthcare has unique characteristics. Patients are not ‘simple’ consumers. One of the Commission’s central responsibilities is the protection of the health of European citizens (Article 152 of the European Treaty). Support for industrial competitiveness must not be allowed to supersede public health interests. Many European citizens and health actors are increasingly worried by the commercialization of healthcare.

**The position of ESIP and MEDEV** on the Commissions proposals regarding information to the general public on medicinal products subject to medical prescription **is based on the following arguments:**

### **Missing evidence for allowing industry to provide information**

ESIP and MEDEV fully acknowledge and support the right of patients to information – provided that it is exhaustive, comparative, unbiased and high-quality information on diseases, their prevention and both medicinal and non-medicinal treatment options.

**Pharmaceutical industry claims to be in possession of key information about its products, which patients cannot get from any other source. But neither the pharmaceutical industry nor the European Commission specifies what this key information may be** nor forwards any evidence allowing industry to provide this information directly to patients and citizens would reduce inequalities in their access to good-quality objective, reliable and non-promotional information on medicinal products.

The proposal is at odds with present legal requirements since the pharmaceutical industry is obliged to provide all relevant 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 public assessment reports and the summary of product characteristics (SPC). These documents 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. In addition adverse effects should be immediately reported to the appropriate authorities. Ensuring complete transparency and universal access to this information should be the primary goal of an EU information strategy on medicines.

The latest Commission proposal would allow industry to selectively provide information directly to the public. It is difficult to see what motivation industry has to provide information if it isn'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 take an informed decision about their medication. In a highly competitive environment that is subject to the constraints of the financial markets, the pharmaceutical companies will defend their medicinal products to the detriment of other preventive or therapeutic means, which makes the "information" they provide promotional by definition.<sup>1</sup>

**It is therefore not acceptable that the pharmaceutical industry disseminates this information to the public directly.** In the opinion of ESIP and MEDEV public health authorities, independent institutes (like the IQWiG in Germany) physicians or pharmacists should be the principal channels for disseminating information on prescription only medicines. Throughout the Member States there are many good examples of good practice with regard to the provision of independent, evidence-based information on medicines. Indeed a number of organisations and institutes responsible for the provision of information at a national level have already established an international reputation. Therefore, any Commission action

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<sup>1</sup> The results of the many consultations on the issue of "Patient information", held by the European Commission (Enterprise and Industry Directorate-General) over 2007 and 2008, have shown that nearly all health stakeholders are overwhelmingly opposed to allowing pharmaceutical companies to communicate directly to the public. The results of this consultation are unequivocal, as is stated in the report by the Commission itself: "The great majority of the respondents had a view that the ban on direct-to-consumer advertising of prescription-only medicines should be maintained, making sure that there is a clear distinction between advertising and non-promotional information. Their obvious conflicts of interest were underlined by the majority of respondents to the consultation: In total, 62% of respondents (85% of the healthcare professionals, 60% of the patients, 75% of the regulatory authorities, 100% of the consumers and 100% of the payers) stated they were opposed to the companies providing information directly to the public, or "accused that there is a lack of a coherent distinction between advertising and information" (cf. European Commission - Enterprise and Industry Directorate-general: Key ideas of a legal proposal on information to patients: summary of the public consultation responses? Source: [http://ec.europa.eu/enterprise/pharmaceuticals/patients/docs/summary\\_public\\_cons\\_220508.pdf](http://ec.europa.eu/enterprise/pharmaceuticals/patients/docs/summary_public_cons_220508.pdf); p.3.

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. This would be a much more efficient and cost-effective solution which at the same time would guarantee the objectiveness of the information.

Instead of creating, controlling and continuously monitoring hundreds or thousands of web-pages of the industry – information could be comprehensively presented in a neutral form on a dedicated website of the respective national independent public authority. Moreover the citizen would then have the possibility to compare information about different medicinal products directly.

### **No clear-cut distinction between advertising and information**

One crucial problem of the Commission's proposal is that there is no clear-cut distinction between advertising and information. On the other hand, the Council demanded this very distinction in its conclusions of 19 May 2008. Even the Commission's own DG SANCO conceded in its far preferable but unfortunately not successful alternative proposal: "As no clear distinction can be drawn between non-promotional information and advertising it is essential that the information and the form in which the information is to be provided to the general public is submitted to prior vetting by the national competent authority to ensure compliance with the rules set out in the Directive."

In the course of a Danish lawsuit the European Court of Justice has also come to the conclusion (C-421/07 of 18 November 2008) that there is no hard-and-fast rule for the distinction between advertising and information, thus requiring the vetting of each individual case, especially with a view to the persons involved and the general conditions. According to the European Court of Justice the line between information and advertising should be drawn on the basis of the question whether the intention of boosting prescriptions, dispensing, sales or consumption of the products concerned is pursued by the campaign.

For example, Article 100 b envisages the provision of information by industry directly to patients about non-interventional scientific studies (also often known as: post-marketing observational studies - PMOS"). The serious danger with this 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. The Commission has recognized in the public consultation on pharmacovigilance (point 3.2.5) that information on such studies is "often of poor quality and frequently promotional".<sup>2</sup>

In 2007, the first vaccination against cancer was introduced onto the market. In Germany, this vaccination against cervical cancer is recommended by a scientific board and is reimbursed by all German health insurers. Despite an ongoing controversial discussion at the scientific level about the therapeutic value, the effectiveness and the long-term effects of the vaccination, already within one year of its entering the market the vaccination has led to additional costs (for the German health insurers) amounting to 250 million Euros. The vaccine market authorisation holder began an information campaign that was focused on the emotions and fears of mothers of not protecting their daughters from contracting cancer, neglecting the open questions about the limitations of the vaccination and information about alternative

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<sup>2</sup> European Commission – DG Enterprise and Industry (5 December 2007): Strategy to better protect public health by strengthening and rationalizing EU Pharmacovigilance: Public consultation on legislative proposals. Point 3.2.5: Codify oversight of non-interventional safety studies (P.6).

treatments. The HPV<sup>3</sup>-vaccination campaign is good example of how an "information" campaign by the pharmaceutical industry focuses on emotions rather than comprehensive health education that would enable citizens to make an informed choice.

Following the new proposal concerning Article 88 not only vaccination campaigns will be allowed but also "other campaigns in the interest of public health". It is the view of ESIP and MEDEV that there is no public health need to extend the scope of this article and doing so would incur significant additional costs for the health systems by stimulating demand beyond what is medically necessary.

### **The current proposal allows industry to "push" information to patients**

Article 100c codifies the authorised information channels:

- Health related publications defined by Member States
- Internet websites
- written answers to requests for information of a patient.

While circulation of information via radio, TV and web-TV remains explicitly prohibited, health related publications, which include for example printed media or dedicated websites, would become an accepted channel for dissemination. This seems contrary to the principle of "pull-mechanisms" (information sought actively by a patient) and constitutes rather an example of a potential "push-mechanism" (information received passively). Hence, the proposal can only be considered an instrument that opens up alternative and innovative ways of DCTA.

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

While the European Commission justifies this directive by the need to tackle unequal access to information for patients in the EU, it actually creates new inequalities in Article 100c, which codifies that health related publications should be defined by Member States. ESIP and MEDEV welcome this recognition of the Member State competence in this field and recall that 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 the best position to make judgments about how information is disseminated.

Rather than creating new inequalities in Article 100c, harmonisation at EU level could contribute to changing the current situation and promoting public health across the EU. This would be of major importance in particular in the era of the Internet where citizens can access information from all over the world. Without following these arguments in the new articles the Commission makes itself implausible and it is hard to believe that the proposal is aiming at putting the interest of patients first. Far from it - it emphasises the impression that the proposal fails to do any of these things because it envisages only one solution and that is the provision of information by industry.

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<sup>3</sup> HPV = human papillomavirus

### **Colourful flyers bring patients no added value as regards their knowledge about a pharmaceutical**

If a patient wants to inform himself about a medicinal product he needs detailed information in order to form a qualified opinion. This kind of information is not what is being proposed by the Commission: a flyer, a notice in the newspaper or a poster about a specific pharmaceutical does not inform the patient. Relevant, high quality and detailed information about which pharmaceutical is the right one for an individual patient can only be given by physicians or pharmacists.

Article 100b c authorizes the provision of "Factual informative announcements" on prescription medicines by the industry, which are of little value for patients' treatment regimes but of enormous value as a form of promotion for the products. They are hugely effective at inflating sales through emotive branding images and messages. **ESIP and MEDEV believe that the pharmaceutical industry should not be given the freedom to produce "free-style" leaflets** which would lead to the situation where two types of leaflets are circulating at once: one, officially approved, the other, a free-style version produced by the manufacturer. In order to make the official, approved leaflet more useful and accessible to patients, Article 59 of Directive 2001/83/EC modified by Directive 2004/27/EC, which specifies the content of package leaflet should be optimized to improve the quality and clarity of labeling and the leaflet.

Furthermore, to make an informed decision the patient must be able to compare different products/treatments. Article 100d specifies that information should not include comparisons between medicinal products, which is right because industry is not able to provide unbiased comparisons; but it should be made clear that this is an important task for the public health authorities and independent institutes.

### **Promotional steering effects of selective information**

Following the Commission proposal, the pharmaceutical industry will be allowed to be selective about which information it provides on a product. Article 100 b allows the presentation and dissemination by industry of information contained in the official SPC and the PIL "in a different way", without adding that this should not be selective information. The obligation to always provide the complete information including risks, adverse effects and contraindications, and not only the positive characteristics, is essential.

Further, while being seen to be 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. A Canadian and an American study have both arrived at the conclusion that advertising results in increased demand for the medicines that have been advertised, especially for lifestyle products and products for symptomatic treatment.

In addition, physicians prescribed the medicines despite judging that 50% of the new prescriptions for the requested DTCA medicines were only “possible” or “unlikely” choices for other similar patients. Consequently, the claim that physicians cannot be influenced is not upheld. The dramatic increase in costs as a result of this behavior can be illustrated again by an example from the United States. The rise in expenditure on medicines in 2000 compared to 1999 amounted to approximately \$ 21 billions. 48% of this increase was due to 50 advertised medicines and 52% was due to 10,000 medicines which had not been advertised.<sup>4</sup>

### **Further shift of expenditures from research and development to marketing activities**

The Preliminary Report of the European Commission DG Competition on the Pharmaceutical Sector Inquiry published on 28 November 2008 states that: "During the period 2000 – 2007 originator companies spent on average 17% of their turnover from prescription medicines on R&D worldwide (approximately 1.5% of turnover was spent on basic research – research to identify potential new medicines, the rest mostly on (pre-) clinical trials and tests). Expenditure on marketing and promotional activities accounted for 23% of their turnover, thus about one third more than they spent on R&D as a whole."<sup>5</sup> The current proposal encourages the pharmaceutical industry to direct even more of its resources towards marketing activities to the further detriment of important research and development (R&D) activities aimed at bringing new products and treatments to patients. Once again, this is not in line with public health interests.

### **With the current proposal the Commission creates an enormous bureaucratic and expensive regulatory system which nevertheless cannot be effective**

The proposed structure for monitoring information would require massively increased resources in the Member States, because it is left up to them to establish national structures for monitoring and enforcement of the new provisions (see Article 100e to 100j).

**All these rules require enormous additional bureaucracy and increased costs at the expense of tax-payers and citizens.** This leads inevitably to the question: Should public authorities use their limited resources to act as law enforcers and to control the pharmaceutical industry or rather be proactive and invest in validated processes towards the provision of independent and comparative information to the general public? This is even more important considering the mass of data which has to be controlled: it is improbable that this system, regardless of the amounts of money spent on it, will ever lead to an effective control.

### **No continuous ex ante control of all information**

For ESIP and MEDEV it is essential that all information regarding medicinal products subject to prescription is controlled before its publication. Although such a general ex ante control is stated in the current proposal (Article 100g), it contains an exception which would provide an important loophole for industry to avoid prior control of the information it disseminates: information does not have to be controlled prior to its dissemination if "the content of the information has already been approved by the competent authorities or an equivalent level of adequate and effective monitoring is ensured through a different mechanism." This can be

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<sup>4</sup> Health Council of Canada (2006): Direct-to-Consumer Advertising of Prescription Drugs in Canada: What are the Public Health Implications? p. 12 et seq.

<sup>5</sup> See: Pharmaceutical Sector Inquiry - Preliminary Report (DG Competition Staff Working Paper) from 28<sup>th</sup> November 2008; p.6 et seq.

assumed for the PIL, SPC, and the public assessment reports. It is unclear in the proposal if this "exception" also applies to other information drawn up by the competent authorities themselves but then presented by industry in a different or selective way. As at present alternative mechanisms of control are not foreseen, both possibilities allow for the uncontrolled dissemination of selective and incomplete information. It will also lead to confusion if patients are faced with incompatible information on the websites of the different marketing authorisation holders, leaving the patients uncertain about what they can believe – definitely not a situation that can be considered to improve the quality of information.

On the entry into force of this proposal the Commission is planning to draw up guidelines concerning information allowed under this title and a code of conduct for marketing authorisation holders providing information to the general public. Whether these guidelines will reduce or replace the currently envisaged ex-ante control by national competent authorities is not stated.

### **Rules for the registration of websites which will result in quality standards of the lowest common denominator**

Dissemination of information via the companies' websites follows different rules. Authorisation holders have to register their website with the national competent authority of the Member State of the country code used by the website, prior to making it available to the general public. If the website does not use a country code, the marketing authorisation holder may select the Member State of registration. This regulation is fundamental, since after registration of the website, the information contained may be provided on any other website throughout the Community if the contents are identical. Moreover, the Member State where the website has been registered is responsible for monitoring the contents. In view of the fact that some Member States are less strict about their interpretation of non-promotional information than others, and that different conditions and recommendations govern the use of pharmaceuticals in the different Member States this provision must be regarded as being highly problematic.

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