



EPHA consultation response

'Legal proposal on Information to Patients'

Subject:	Consultation response: ' Legal Proposal on Information to Patients'
Date:	7 April 2008

The European Public Health Alliance (EPHA) is the largest European Platform representing approximately 100 members working in the field of health. Our membership is unique in its diversity: the following statement is supported by representations from patient groups, healthcare professionals, public sector bodies, disease-specific organisations, treatment groups and others. Our membership includes representatives at international, European, national, regional and local level.

EPHA's mission is to protect and promote public health in Europe.

EPHA brings together organisations across the public health community, to share learning and information and to bring a public health perspective to European decision-making. We help build capacity in civil society participation across Europe in the health field, and work to empower the public health community in ensuring that the health of European citizens is protected and promoted by decision-makers. Our aim is to ensure health is at the heart of European policy and legislation.

Please see www.eph.org for more information.

This document is a response to the European Commission Directorate General 'Enterprise and Industry' consultation on a 'Legal proposal on Information to Patients' . The response was developed on the basis of extensive consultation with the EPHA membership.

A final response was submitted to the Commission on 7 April 2008.

The response focuses on three main areas:

- 1.Objectives of the proposal
- 2.Advertising vs. information
- 3.Regulating the provision of information

This response deals largely with the principles behind the consultation. It should be read in conjunction with the Commission's consultative document and the individual responses of EPHA members.



EPHA consultation response

'Legal proposal on Information to Patients'

Executive Summary

EPHA believes that the current EU legislation regarding the prohibition of advertising on prescription-only medicines **should not be relaxed in any way** including the manner proposed by this consultation. EPHA is concerned that this consultation is proposing 'advertising' under the banner of 'information provision.'

EPHA calls for a **clear distinction** between:

- Information to Patients
- Information on Medicines
- Health Information

EPHA believes this proposal is confusing in the way it addresses these **three distinct areas** of information provision and that this needs to be resolved in order to prevent further confusion.

EPHA believes that this proposal **does not address** its expressed 'core intention' of ensuring '*that all EU citizens have access to good-quality, objective, reliable and non promotional information on prescription-only medicinal products*'. On the contrary, it **opens the market for advertising** on prescription only medicines to the general public under the legal guise of information provision.

EPHA believes that healthcare professionals should remain the primary source of health information, and that any new proposed measures support their role as medical experts in advising patients of the most appropriate treatments for their conditions, in their circumstances.

EPHA strongly suggests the Commission to focus first on methods to improve the quality of information on prescription medicines to patients. EPHA believes that until this has been achieved, any changes to the current status quo would not benefit European patients or the general public.

EPHA recommends general health-information should be addressed separately from any regulation governing pharmaceutical products and should meet specific quality criteria.

EPHA reiterates its deep concern over the **lack of transparency** and representation in the role and set up of the Pharmaceutical Forum, whose conclusions have been both taken up as legitimate in the present legal framework as well as used as reference criteria.

EPHA has concerns about the Impact Assessment study outsourced by the Commission to Europe Economics. The process has been surrounded by a severe lack of transparency and its results are not yet available. **EPHA stresses the necessity of a complete Impact Assessment prior to the discussion of any changes to the present legislation.**

EPHA calls for the responsibility for 'Information to Patients' to move from DG Enterprise & Industry to DG SANCO given its responsibility for health and health information. It is highly inappropriate for this to be led by any part of the Commission other than DG SANCO whose responsibility is the health of European citizens.



EPHA consultation response

'Legal proposal on Information to Patients'

EPHA Response

1. General Comments

Whilst EPHA agrees with the principles behind this proposal, we do not believe that the present proposal will solve the problem of “unequal access of patients and the public at large to health information”. The proposal does not demonstrate how it will improve the current situation.

EPHA questions the proposal's ability to address the need for “objective, unbiased, patient-oriented, evidence-based, up-to-date, accessible, transparent, relevant and consistent” information. There is nothing in this proposal that clarifies how this information will be assured.

The Commission proposes that all information provided to citizens should fulfil specific criteria concerning the quality of the information. It stresses that regarding quality criteria, comparisons between medicinal products should not be allowed¹. EPHA questions the effectiveness of providing additional information on products without the fundamental comparison of which treatment is most effective. **The added value of improving the information to patients about medicines is in building up the skills of patients themselves to evaluate the information available.** This will improve their ability to make increasingly informed decisions and eventually lead to cost-savings for healthcare systems.

EPHA is concerned that this proposal does not provide for alternatives to pharmacological interventions. There is a need for a body to provide healthcare professionals and patients with information on evidence based approaches to health care. Information on **all** the effective treatment options would be a better result for the health of citizens and patients and for public health as a whole.

2. Objectives of the proposal

2.1 Purpose of the proposal

According to the Commission consultation document the purpose of the ‘Information to Patient’ proposal is:

- a) to ensure good quality, objective and reliable, non promotional information on prescription-only medicinal products.

- (b) to harmonise the existing situation in Member States.

¹ European Commission 'Legal Proposal on Information to Patients' 5 February 2008, p.7



EPHA consultation response

'Legal proposal on Information to Patients'

EPHA agrees with the aim and the identified need for good quality, objective, reliable and non-promotional information on prescription-only medicines, as for information on medicines in general, but **does not believe the present consultation addresses this objective** and therefore questions how the Commission proposes this is delivered.

EPHA welcomes the idea to harmonise the existing situation in Member States as long as this means **raising standards towards the best-practice available** NOT reducing standards to the lowest common denominator.

2.2 Policy objectives

In the current proposal, the Commission is pursuing three policy objectives:

- i. Establish a framework, which provides citizens of EU Member States (MS) with information about the benefits and risks of their prescription medicines.
- ii. Maintain the ban on direct-to consumer advertising of prescription medicines.
- iii. Avoid unnecessary bureaucracy.

With regards to the first policy objective on risks and benefits of prescription medicines, EPHA strongly calls for a first step towards this objective: **ensuring the free availability of accurate information on the risks associated with prescription medicines.**

For EPHA it is not clear what the Commission means by “set rules on the provision of information by marketing authorisation holders” when citing this as a mechanism for delivery, and therefore EPHA questions its ability to deliver the above policy objectives. Neither is it clear how such a proposal will avoid unnecessary bureaucracy.

3. Advertising vs. Information provision

EPHA does not agree with this proposal as a solution to clarify the rules on information provided by pharmaceutical companies on prescription-only medicines. EPHA does agree that advertising should remain prohibited.

The Commission states that communication not covered by the definition of advertisement should be regarded as information and that clear criteria should distinguish the information that is ‘allowed’ from the information that is ‘not allowed’². **EPHA believes that the scope, content and general**

² European Commission 'Legal Proposal on Information to Patients' 5 February 2008, p.6



EPHA consultation response

'Legal proposal on Information to Patients'

principles of the new legal provisions (being proposed) will create legal uncertainty between advertisement and information provision.

The Commission states that “under the clear safeguard that all advertisement to the public is banned” it should be possible for the pharmaceutical industry to disseminate information on prescription-only medicines³. **EPHA believes that this is a contradiction and that to 'disseminate information' in this context is paramount to advertising.** EPHA believes that this proposal in its definition of 'information provision' is advocating direct-to-consumer advertising. Its definition is unworkable. This is in essence, a proposal to relax the existing rules banning direct-to-consumer-advertising of prescription medicines to the public, which is not supported or acceptable.

The Commission proposes that a distinction between 'advertising' and 'information' would create a framework for the pharmaceutical industry to provide selected information on their products to the public that would inevitably be positively biased. The Commission considers that the creation of such framework would enable EU citizens to receive “objective information from a reliable source.” **EPHA believes there is a fundamental conflict of interest between the business interests of the pharmaceutical industry and its ability to become primary provider of 'objective' and unbiased information.**

The Commission states that “a distinction” should be made between the cases where the patient is passively receiving the information (push) or actively searching for the information (pull) in terms of the monitoring mechanism⁴. In some cases the distinction is easy: an advertising board or a TV advert are examples of 'push'. Doing an internet search, or opening a magazine are examples of 'pull'. The distinction blurs when a video stream of a TV show including information on a product is actively downloaded. Currently there is no regulation of the manner in which the pharmaceutical industry's information is fed to prescribers and no control over how that prescriber then “selects” the product for that end-user or patient.

4. Regulating information provision

4.1 The role of the pharmaceutical industry

The proposal states⁵ that the information to be allowed should be compatible with approved summaries of product characteristics and patient information leaflets. EPHA is sceptical whether true objectivity could be achieved if the pharmaceutical Industry provides scientific expertise

3 European Commission 'Legal Proposal on Information to Patients' 5 February 2008, p.6

4 European Commission 'Legal Proposal on Information to Patients' 5 February 2008, p.6

5 European Commission 'Legal Proposal on Information to Patients' 5 February 2008, p.6



EPHA consultation response

'Legal proposal on Information to Patients'

without the presence of a 'watch dog' acting as middleman. EPHA believes any new rules should strengthen the ban on advertising and preclude industry from posting its information on prescription only medicines on the internet, unless via an impartial and independent third party.

The drug safety and effectiveness data submitted to regulatory authorities should be publicly available, including ALL pre-market laboratory and clinical data and post-marketing studies. This is data essential to prescribers and patients. **Information on the relative efficacy and effectiveness of a medicine is of vital importance – information on non-treatment options should also included.** The pharmaceutical industry has an insurmountable conflict of interest when providing any information about their products to the general public.

4.2 The role of national co-regulatory bodies

The Commission proposes that when industry disseminates information on prescription medicines through websites or orally, they should announce such activities to a national co-regulatory body, which should monitor the contents⁶. EPHA does not see how the provision of information – whether active or passive - through internet websites or orally can be easily regulated to ensure 'unbiased information.' EPHA questions the ability of national co-regulatory bodies to control this unbiased information distributed in this manner.

A starting point would be to establish a '**central**' **database of existing relevant and unbiased information about medicines**. A central database at European level, such as EudraPharm which is in development, could provide more information for health care professionals, provided that technical access was improved and language barriers reduced, so that equal access could be guaranteed.

Until recently, antitrust bodies in Member States (MS) and at European level have refrained from confronting the pharmaceutical industry as it poses particular challenges for regulators. Any regulatory body to be established would have to have strong foundations and clear remits to be able to tackle directly a powerful lobby whose influence is deeply rooted and felt not only by healthcare professionals, but also by policy-makers and the public at large.

6 European Commission 'Legal Proposal on Information to Patients' 5 February 2008, p.7



EPHA consultation response

'Legal proposal on Information to Patients'

5. Concluding remarks

EPHA representing its members believes that all Europeans, no matter their disease, condition, background or nationality, have the right to access objective quality information about their health, medical conditions and the best available treatments for their condition. This should be a fundamental principle when discussing providing information on medicines. Rather than focusing on pharmaceuticals alone, the focus should move towards one of defining the range of possible treatments for each condition, including the available pharmaceuticals as one option.

EPHA believes that the Commission can make a significant contribution towards achieving this goal, with the right approach and implementation.

EPHA believes strongly that this subject and its discussion should be **'owned and led'** by DG **SANCO**, as it has the responsibility for health protection and promotion. **This is an issue of public health and not one concerning the regulation of industry.** Hence, **EPHA calls on the Commission to establish DG SANCO as the leading force in this discussion.**

EPHA believes it is both inappropriate and ill-intended for the European Commission to release such a high-impact proposal, before disclosing the results of the impact assessment study. EPHA questions the legitimacy of a proposal pushed through the legislative process without due impact assessment.

Any EU action on provision of medicinal information **should not contribute to an increase in the existing health inequalities**, either by disseminating information in inaccessible language or other means. Any proposal that would stimulate a demand-driven pharmaceutical market in Europe would undermine the principles of accessibility and sustainability as agreed by the 2006 European Council Conclusions on Common values and principles in European Union Health Systems.

EPHA strongly believes that this proposal would undermine the spirit of the existing article 88a of Directive 2001/83/EC which bans advertising of prescription only medicines directly to the patient/consumer.

We urge the Commission to reconsider its approach and the implications that any liberalisation of existing rules will have on demand, supply and sustainability and patient safety within healthcare systems.