

○ Legal Proposal on Information to Patients

A RESPONSE FROM THE PICKER INSTITUTE
EUROPE TO THE PRELIMINARY PROPOSAL BY
THE DIRECTORATE-GENERAL FOR ENTERPRISE
AND INDUSTRY

MARCH 2008

About Picker Institute Europe

Picker Institute Europe is a non-profit charity with its head office in the UK, which works with patients, professionals and policy makers to promote understanding of the patient's perspective at all levels of healthcare policy and practice. It undertakes a unique combination of research, development and policy activities which together work to make patients' views count.

The work of the Picker Institute ranges across all patients, including patients from all condition and disease groups and in all healthcare settings. Picker Institute Europe has no vested interest in the provision of information on any particular pharmaceutical product or on the treatment of any specific disease.

The Picker Institute is a leading authority on patient-centred healthcare. It supports the 'partnership' approach to healthcare in which health professionals and patients work together to make shared decisions on the available care and treatment options.

Information and communication are central to this process, and therefore the Picker Institute has developed considerable expertise in researching the information needs of patients.

The Picker Institute's work on patients' information needs includes:

- developing, piloting, co-ordinating and implementing patient experience surveys
- Independent research studies including international comparisons
- an authoritative study of all the international evidence on 'patient-focused interventions', examining over 130 systematic reviews and many randomised controlled trials
- research projects with partners including the UK's Department of Health and many non-profit patient-oriented organisations including various condition- or disease-specific studies.

Picker Institute Europe was represented on the high level task force 'G10 Medicines' which reported to the European Commission in 2002.

In the UK Picker Institute Europe is an adviser to the Department of Health on information, choice and shared decision-making.

Overall response

Picker Institute Europe welcomes the opportunity to respond to the preliminary proposal to allow pharmaceutical companies to provide direct-to-consumer information about prescription-only medicines.

The Picker Institute strongly supports and advocates for consumer access to accurate, complete and impartial information about health, healthcare and treatment options.

Further, the Picker Institute agrees that there are unacceptable variations in health and medicines information provision across the Member States and EEA, and would wholeheartedly support genuinely patient-focused initiatives to ensure equality in the provision of, and access to, information.

The Picker Institute calls on the European Commission to develop and implement a multi-agency medicines information strategy to address the inequalities in information provision and access that it has identified.

However, the Picker Institute strongly opposes the current single-agency preliminary proposal to allow pharmaceutical companies greater freedom to provide information about prescription-only medicines directly to consumers. The Picker Institute calls on the Commission to reconsider its plan to proceed to a formal legal proposal.

The Picker Institute's opposition is based on the following grounds:

1. the proposal is clearly driven by the pharmaceutical industry's interests - not by the interests of patients
2. the Commission's report COM(2007) 862, describing its review of Member States' provision of medicines information, does not support the proposal
3. the Commission's report COM(2007) 862, and the preliminary proposal purportedly based on its findings, are not supported by consultation responses to the draft report
4. the Commission's review process and preliminary proposal do not fulfil the obligations placed on the Commission by Directive 2001/83/EC
5. the preliminary proposal depends on there being a workable distinction between 'advertising' and 'information', but no groundwork has been done to develop the necessary EU-wide definitions and distinguishing criteria
6. in the absence of the necessary groundwork, the distinction between 'advertising' and 'information' will in practice be unworkable and the proposal, if enacted, would have the effect of undermining the ban on direct-to-consumer advertising.

Response in detail

1. The proposal is clearly driven by the pharmaceutical industry's interests - not by the interests of patients

The Commission's stated intention is to put the interests of patients first, yet there is no evidence to suggest that the preliminary proposal addresses patients' interests, needs or wishes.

The Picker Institute's view is that the exclusive focus on allowing pharmaceutical companies to provide direct to patient/public information conflicts with the stated intention.

The Picker Institute wishes to point out, in particular, that the proposal does not reflect the evidence-base regarding patients' information needs, which shows that the most significant unmet need is for **comparative and comparable** information to enable patients to make informed decisions on the most appropriate treatment for them.

In discussing drugs that are legally available without prescription, the World Health Organisation states that:

'Advertisements to the general public should help people make rational decisions on the use of drugs.....' (Advertisements in all forms to the general public. Ethical Criteria for Medicinal Drug Promotion. WHO. 1988)

The Picker Institute agrees that patients should be able to make rational decisions, but advertising (i.e. promotion of individual products) does not support this. Patients need information that enables them to compare and choose between:

- treatment and no treatment
- off-prescription and prescription-only medicines
- different prescription-only drugs and formulations
- medical and surgical treatment options.

The European Commission Directive 2006/114/EC provides an EU-wide framework regulating misleading and comparative advertising. For the purposes of that Directive, 'comparative advertising' is defined as '*any advertising which explicitly or by implication identifies a competitor or goods or services offered by a competitor*'.

The Picker Institute notes that 'comparative advertising' is permitted, subject to certain conditions, by Directive 2006/114/EC.

Thus, under Directive 2006/114/EC, pharmaceutical company advertising of prescription-only medicines to **licensed prescribers** can include information that compares different options and products.

Similarly, pharmaceutical company direct-to-consumer advertising of over-the-counter medicines can include comparative information.

The Commission's preliminary proposal to allow direct-to-consumer 'information', however, explicitly prohibits 'any comparative sections between medicinal products' - so information to patients and the public about prescription-only drugs could not include information that would allow consumers to compare different products.

This clearly demonstrates that the pharmaceutical industry's interests are the priority, not patients' interests.

2. The Commission's report COM(2007) 862, describing its review of Member States' provision of medicines information, does not support the proposal

The Picker Institute's view is that the Commission's report:

- **supports** the development of detailed EU-wide provisions concerning provision of information
- **supports** the development of EU-wide medicines information quality criteria and quality standards
- **supports** harmonisation of information provision by Member States' Competent Authorities, via the Internet and other platforms
- **does not support** a legal proposal to allow the pharmaceutical industry to communicate directly with patients and public about prescription-only medicines.

In examining patient information benefits and risks, the Commission's report states that:

- EU citizens have unequal access to information, and that the lack of detailed provisions concerning provision of information in Community legislation may lead to inequality in access for patients in the different Member States
- the lack of EU quality standards for information to patients increases the risk of wrong, misleading or confusing information creating health risks, and compounds inequalities in access to information across Member States
- lack of information may lead to uninformed choices, and that not using existing possibilities (ie Internet technologies and paper formats that link specific medicines information with related information) throughout the EU means perpetuating existing practices of uninformed choices including late diagnosis, or lifestyle based on low risk awareness.

The Picker Institute's view is that the Commission's review and report are superficial, and do not adequately explore either the extent of information inequalities, or the relationship between information inequalities and health inequalities. Nonetheless, the

report's assessment of information benefits and risks is plausible and is supported by evidence from other sources, including the high level task force G10 Medicines report.

There is therefore a clear case for adopting an EU-wide, multi-stakeholder approach to ensuring consistency in the type, format and quality of information available to EU citizens. There is no case – other than industry interests – for the Commission's preliminary proposal.

3. The Commission's report COM(2007) 862, and the preliminary proposal purportedly based on its findings, are not supported by consultation responses to the draft report

The Commission's draft report was issued for consultation on 19th April 2007. The Commission received 73 responses in total, of which 18 were from pharmaceutical organisations and companies.

The Picker Institute responded to the draft report consultation. This response:

- welcomed the draft report's statement that: 'there is little support for information provision [by the pharmaceutical industry] without a demand from patients'
- restated the Picker Institute's support for the G10 Medicines recommendations regarding advertising and information
- questioned the report's conclusion that the pharmaceutical industry should be allowed a greater role in the provision of information to patients
- called upon the directorates-general for Enterprise and Industry and for Health and Consumer Protection to identify information barriers and appropriate solutions, and to determine the priority actions at European level.

(http://www.pickereurope.org/Filestore/News/Picker_Institute_response_to_EC_patient_information_report.pdf)

On the issue of advertising and information, the Commission's own summary of consultation responses describes:

- consensus on the need to improve information provision
- consensus in favour of maintaining the prohibition on direct-to-consumer advertising of prescription-only medicines
- lack of consensus regarding whether a clear distinction can be made between advertising and information
- lack of consensus regarding whether new EU legislation was necessary to improve information provision

- lack of consensus regarding the role of pharmaceutical companies as a source of information for patients and public.

The Commission's summary states that:

'A large number of stakeholders supported the provision of information to patients on medicinal products for human use. However, this was separated from the notions of 'direct to consumer' or 'direct to patient' advertising by the industry, which was not looked upon favourably. Some contributions emphasised the role of patient information leaflets accompanying each medicine, while others suggested that the improvement of the availability and quality of patient information requires legal action'.

(http://ec.europa.eu/enterprise/pharmaceuticals/pharmacos/docs/doc2007/2007_10/d-34327-summary-of-consultation-responses.pdf)

The final report's conclusion on the way forward 'in view of public consultation responses' is as follows:

'Opinions expressed on the way forward converged as regards the needs to improve information to patients, to adopt common standards and quality criteria, to distinguish between advertising and information and to keep the ban on direct to consumer advertising on prescription-only medicines, and the recognition of the Internet as an important information channel. Different views were expressed on how to improve provision of information to patients, on the role of the pharmaceutical industry and on the mechanisms to regulate and enforce applicable rules.

On the basis of the outcome of this consultation, the Commission intends to propose to the European Parliament and the Council amendments to the current rules on the provision of information to patients by the end of 2008. This proposal will put the interests of patients first and with this perspective should aim at reducing differences in access to information and should ensure the availability of good-quality, objective, reliable and non promotional information on medicinal products.

The Picker Institute's view is that the Commission's preliminary proposal entirely disregards:

- the direction of the consultation responses
- the lack of - and importance of - stakeholder consensus.

The Picker Institute's view is that the Commission's December 2007 final report and subsequent preliminary proposal reflect the pharmaceutical industry's interests rather than the consultation responses.

4. The Commission's review process and preliminary proposal do not fulfil the obligations placed on the Commission by Title VIII Article 86 of Directive 2001/83/EC

European Commission Directive 2001/83/EC forms part of the European Community legal framework covering the authorisation and market surveillance of medicinal products for human use.

Title VIIIa Article 88a of Directive 2001/83/EC states that:

'Within three years of the entry into force of Directive 2004/726/EC, the Commission shall, following consultation 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.'

*'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'. [our emphasis]*

The Picker Institute considers that:

- the Commission's method of data collection and level of analysis do not fulfil its Directive 2001/83/EC obligations
- the consultation with stakeholders required by 2001/83/EC should have formed part of the data collection process, rather than being limited to an opportunity to comment on a draft report
- the Commission should abandon its preliminary proposal and proceed directly to the development and implementation of a patient-focused EU-wide medicines information strategy.

In response to Title VIII Article 86 of Directive 2001/83/EC the Commission services conducted a survey in 2006 of information provision by Medicines Regulatory Agencies. This self-reported survey data was complemented with information from members of the Pharmaceutical Forum Information to Patients Working Group, which has no representation from European Union consumer organisations.

Following consultation on the draft report, the Commission's final report COM(2007) 862 was published on 12th December 2007.

In this report, the analysis of current practices required by 2001/83/EC comprises a brief overview of information received from Member States Regulatory Agencies about medicines and/or illness information initiatives.

This overview concludes that *'a profound assessment on the perception of the different practices in Member States is not available'*.

However, the report does state that:

'Based on the information received, there are a significant number of initiatives of varied nature which intend to provide information on medicines and/or illnesses to healthcare professionals and the public. Accurate information on medicines is available from many sources, for example from physicians, pharmacists, pharmaceutical companies, medicines' regulatory authorities, health professional and scientific organisations and patient and consumer groups. Patients can use libraries, drug bulletins and other information services to access information.

'Probably the most important difference between Member States is the type of information that can be made or is available to the public on the Internet. Some adopt a stricter approach while others allow more information for the public on the Internet'.

The Picker Institute calls on the Commission to meet its obligations under 2001/83/EC - having identified inequalities in access to information across the Member States and other EEA countries, the Commission should now consider it appropriate to develop and implement a medicines information strategy.

The strategy should be developed by a genuine multi-stakeholder group, and should aim to ensure that:

- EU citizens have equal access to good-quality, objective, reliable and non-promotional information on medicinal products and other treatments, that enables comparison between options and products
- all Member States Competent Authorities assume responsibility for making medicines information available and accessible to citizens via all delivery platforms, including the Internet
- all stakeholders are engaged in developing a clear, workable distinction between 'advertising' and 'information'
- the prohibition on direct-to-consumer advertising of prescription-only medicines remains and is observed
- regardless of origin and delivery platform, all information about prescription-only medicinal products and other treatments complies with an EU-wide set of drafting and development guidelines, quality criteria and quality standards
- information quality criteria and standards are based on best available evidence about patient and public information needs, **including** comparative information
- information quality criteria and standards cover, but are not confined to, the needs of patients and public who seek information on the Internet
- all prescription-only medicines information is scrutinised and approved by a Member State private/public partnership, or similar multi-stakeholder agency, before publication

- any communication about prescription-only medicines provided direct (ie without independent scrutiny and approval) to consumers by pharmaceutical companies should be regarded as ‘commercial communication’ and regulated accordingly.

5. The preliminary proposal depends on there being a workable distinction between ‘advertising’ and ‘information’, but no groundwork has been done to develop the necessary EU-wide definitions and distinguishing criteria

The Commission’s preliminary proposal states that *‘the (proposed) revision should clarify the rules on information provided by pharmaceutical companies on prescription-only medicines. Basically, communication not covered by the definition of advertisement, should be regarded as information. Clear criteria should distinguish the information that is allowed from the information that is not allowed’*.

The Picker Institute’s view is that the prevailing rules are very clear, while the distinction between ‘information’ and ‘advertising’ is not. There is no single ‘definition of advertisement’ – it is characterised in various ways by different industrial sectors, media platforms and Member States’ regulatory provisions.

The importance of being able to distinguish between ‘advertising’ and ‘information’ was addressed in 2002 by the G10 Medicines’ recommendation that:

‘consideration should be given by the European Institutions, as part of their current review of the pharmaceutical legislation, to: in co-operation with all stakeholders to produce a workable distinction between advertising and information that would allow patients actively seeking information to be able to do so, and to develop standards to ensure the quality of such information.....’¹

To date, no work has been done to address this recommendation. The Picker Institute’s view is that work to address the G10 Medicines’ recommendation should be carried out, and that this should be done:

- **within** the context of developing a European strategy to ensure good-quality, objective, reliable and non-promotional information on medicinal products and other treatments, and
- **before** the development of any legal proposals whose implementation would depend on Europe-wide definitions and criteria to provide a workable distinction.

The Commission’s preliminary proposal rests entirely on whether there can be:

- workable and enforceable distinctions between advertising and information, and between ‘allowed’ and ‘not allowed’ information

¹ High Level Group on innovation and provision of medicines in the European Union: recommendations for action. European Commission. Brussels 2002.

- a genuine distinction between information and non-promotional information, when that information is developed and disseminated by companies with a commercial interest in the product.

The relevant Commission staff working document SEC(2007)1740 (Brussels, 18th December 2007) states that ‘the provisions of Directive 2001/83/EC address specifically the definition and rules on advertising’.

This is not the case. Title VIII Article 86 of Directive 2001/83² does not define ‘advertising’. Rather, it provides examples of the **type of activities** that ‘advertising medicinal products’ shall include. The relevant text is as follows:

‘For the purposes of this Title, ‘advertising of medicinal products’ shall include any form of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products; it shall include in particular the advertising of medicinal products to the general public’

‘Advertising’ is, however, variously defined in other European Commission Directives and regulatory frameworks. For example:

- For the purposes of Directive 2006/114/EC (relating to misleading and comparative advertising), advertising means ‘the making of a representation in any form in connection with a trade, business, craft or profession **in order to promote the supply** of goods or services, including immovable property, rights and obligations’ [our emphasis]
- For the purposes of Directive 2003/33/EC (tobacco advertising) advertising means ‘any form of commercial communications with **the aim or direct or indirect effect** of promoting a tobacco product’. [our emphasis]
- The FAO/WHO Codex Alimentarius Commission defines advertising as ‘any commercial communication to the public, by any means other than labelling, in order **to promote directly or indirectly**, the sale of intake of a food through the use of nutrition and health claims in relation to the food and its ingredients’. (ALINORM 07/30/22; our emphasis).

The Commission services consultation on the draft report found a lack of consensus regarding whether there is a clear distinction between advertising and information – the majority view was that there is no clear distinction.

The Commission’s summary of public consultation responses states that:

‘Generally, healthcare professionals did not think that there was a clear distinction between information and advertising’.

² Directive 2001/83/EC comprises a European Community code governing the production, distribution and use of medicines. Title VIII of the Directive provides a framework governing medicines advertising activities across the Community. It allows direct-to-consumer advertising of off-prescription medicines, and advertising of prescription-only medicines to licensed prescribers. With the exception of approved vaccination campaigns, direct-to-consumer advertising (ie pharmaceutical company advertising to patients and the public) of prescription-only medicines is prohibited.

Among pharmaceutical industry associations and companies:

'views were divided on whether there was a clear distinction between information and advertising, with some suggesting the distinction is something which needs to be clarified'.

The Picker Institute's view is that, in the absence of an agreed definition of 'advertising' and a workable and enforceable distinction between 'advertising' and 'information', the Commission's preliminary proposal should not proceed.

6. In the absence of the necessary groundwork, the distinction between 'advertising' and 'information' will in practice be unworkable and the proposal, if enacted, would have the effect of undermining the ban on direct-to-consumer advertising

According to available definitions of advertising, the key characteristics relate to content, intention and effect. Specifically:

- the inclusion of a **product claim**, and/or
- the **intention to promote** prescription, supply, sale or consumption, and/or
- a **direct or indirect effect** of product promotion.

We explore these three characteristics in the following sections.

Product claims

For the purpose of Title VIII Article 86 of Directive 2001/83, factual, informative announcements and reference material are not covered by advertising rules *'provided they include no product claims'*.

Likewise the UK definition of 'advertisement' in relation to medicines excludes *'reference material, a factual informative statement or announcement, a trade catalogue or a price list' provided that it makes no product claim'* (Medicines (Advertising) Regulations 2(2), Medicines Act 1968 amended).

Similarly, the UK definition of 'advertisement' includes spoken representations, but *'does not include the making of a factual, informative statement or announcement which includes no product claim'*.

The relevant Commission staff working document SEC(2007) 1740 discusses the role of the pharmaceutical industry in the provision of information to meet patient needs. It states that:

'Pharmaceutical companies provide all the data required demonstrating the quality, safety and efficacy of medicinal products, namely pharmacokinetic and pharmacodynamic documentation they have collected from the drug development studies,

including results from clinical trials, to regulatory authorities. It is also their responsibility to provide the pharmacovigilance related information and results from post-authorisation studies related to the safety, efficacy and utilisation of medicinal products. All this documentation is evaluated by drug regulatory authorities during the marketing authorisation process. Thus, pharmaceutical companies possess key information about their products which only in part (through leaflets and labels) is made available to patients'. (Annex 1V: The patient needs on the provision of information).

From this, it is clear that the **quality, safety, efficacy and utilisation** are the key items of information that the Commission is proposing to allow pharmaceutical companies to provide directly to patients and public.

The Picker Institute's position is that direct-to-patient/public information about an individual product's quality, safety, efficacy and/or utilisation by the manufacturers or suppliers of the product would be indistinguishable from a product claim and so should be classified as advertising.

Intention to promote prescription, supply, sale or consumption

The Commission's preliminary proposal argues that the aim of allowing the pharmaceutical company to provide information directly to patients and the public is to reduce inequalities in access to good quality information.

The Picker Institute's considers this to be at best disingenuous, at worst a cynical attempt to exploit information and health inequalities experienced by Member State citizens.

The Picker Institute's view is that the intention of pharmaceutical companies providing direct to consumer information about prescription-only medicines could only be one or other of the following:

- to promote prescription, supply, sale or consumption, or
- to have no impact on prescription, supply etc, or
- to reduce or limit prescription, supply etc.

The Picker Institute cannot envisage circumstances in which pharmaceutical companies would wish to provide direct-to-consumer information that was intended to reduce or to have no impact on the demand for products.

Direct-to-consumer information provided by companies with a commercial interest would inevitably aim to promote uptake of the product.

Whether promotion works **directly or indirectly** - by influencing the behaviour of patients, licensed prescribers and/or the dialogue between them - the underlying **intention** would be likely to be to promote sales.

Direct or indirect effect of promotion

Directive 2003/33/EC, which prohibits advertising of tobacco products, defines advertising as:

'any form of commercial communications with the aim or direct or indirect effect of promoting a tobacco product'.

The Picker Institute's position is that:

- for the pharmaceutical industry, the primary intention for disseminating information would be likely to be that of promoting, directly or indirectly, prescription and use of its products
- in particular, the pharmaceutical industry may wish to provide information to patients and the public in order to influence the dialogue between clinicians and patients, increasing demand for new products and for established brands
- pharmaceutical company information provided direct to patients/public will very likely have the direct or indirect effect of promoting products - even if the information material does not fall within a definition of 'advertising'.

Taking the preliminary proposal together with the Commission's report and its staff working document, it is clear that the pharmaceutical industry's primary interest is in audiovisual, including Internet, provision of information.

The Picker Institute's view is that any direct-to-consumer information provided audiovisually by a pharmaceutical company about its own prescription-only medicines would inevitably be a form of commercial communication, as defined by Directive 2007/65/EC³:

*'...images with or without sound which are designed to promote, **directly or indirectly**, the **goods, services or image** of a natural or legal entity pursuing an economic activity. Such images accompany or are included in a programme in return for payment or for similar consideration or for self-promotional purposes'. [our emphasis]*

Under Directive 2007/65/EC, if a medicinal product or medicinal treatment is available only on prescription in the Member State within whose jurisdiction the media service provider falls, audiovisual commercial communication via that media service provider is prohibited. Audiovisual commercial communication includes, but is not confined to, advertising.

If the Commission's preliminary proposal were enacted, it would be for individual Member States' agencies, including the various healthcare, medicines and media regulators, to determine, on a case by case basis, whether or not audiovisual

³ This directive was updated in 2007 specifically to ensure that it covered not only 'traditional' audiovisual media but also 'non-linear' AV media provided on-line or on demand.

pharmaceutical company information about a prescription-only medicine was designed to promote, directly or indirectly, the 'goods, services or image' of that company.

Within and across Member States' media service providers, media regulatory authorities and medicines competent authorities, there are likely to be differences in interpretation and disagreements about what pharmaceutical company information is 'designed' to do. There are also likely to be differences in the way that audiovisual commercial communications are monitored, and how effectively prohibitions are enforced.

The Picker Institute's conclusion is that the Commission's preliminary proposal undermines the clarity, the principles and the purpose of the prohibition on audiovisual commercial communications about prescription-only medicines. In doing so, it risks undermining the protection that the prohibition currently provides for patients and the public.

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