



## LEGAL PROPOSAL ON INFORMATION TO PATIENTS

### ABPI contribution to the public consultation

#### Introduction

---

**The Association of the British Pharmaceutical Industry (ABPI)** is the trade association for more than 75 companies in the UK producing prescription medicines. Its member companies research, develop, manufacture and supply more than 80 per cent of the medicines prescribed through the National Health Service (NHS).

The ABPI also represents companies engaged in the research and/or development of medicines for human use. In addition, its general affiliate membership is for all other organisations with an interest in the pharmaceutical industry.

The ABPI is a member of EFPIA, the European Federation of Pharmaceutical Industries and Associations, and fully supports EFPIA's submission in relation to the consultation.

We would like to express our thanks for the work done so far by the European Commission and the Commission's vision to put patients and their rights first, which we fully endorse. However, although the Commission is seeking to harmonise access to information about medicines and treatments, we strongly urge the Commission to ensure that this will not mean creating a more restricted environment for UK patients than is currently the case.

## Background

---

The ABPI supports the objectives set out in the consultation under 2.2 that it 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’. ABPI is working in partnership with patient groups and the Department of Health to ensure that patient’s information needs are put first. The UK with its long history of effective self-regulation and its practice of partnership working with other stakeholders to provide non-promotional information about medicines to patients offers a valuable experience that should be taken into account in the development of EU policy on provision of information for patients and the public.

We welcome the opportunity to comment on the ‘Legal Proposal on Information to Patients’ by the European Commission’s Enterprise and Industry Directorate General. We have set out below our response to the draft legal framework and highlighted areas that we feel need further clarification and added detail. We would very much like to stress that we are pleased that the European Commission recognises that the pharmaceutical industry has a role in the provision of information about medicines. This will benefit patients and reflects their increasing demands for information. The prohibition in the Directive (2001/83/EC) to advertising prescription only medicines (POMS) to the public is not clearly restricted only to the marketing authorisation holder. A similar approach should be taken for the provision of information about prescription only medicines to the public. We therefore ask the European Commission to ensure that standards set for the provision of information about medicines by the pharmaceutical industry apply to all information providers.

Below we have listed a summary of the key issues followed by a more detailed explanation.

### Summary of key issues

- The ABPI is pleased that the European Commission aims to make good-quality, objective, reliable and non-promotional information on medicinal products easy accessible for patients, but we call on the Commission to ensure that the aim of harmonising access to information will not mean a restriction of current access for UK patients.
- We are pleased that the European Commission acknowledges that the industry has a role to play in providing information.
- All EU member states should be encouraged to seek ways in supporting wider access to non-promotional medicines information provided by the pharmaceutical industry, patient groups, governmental bodies and others in order to enhance the patient journey and address their patient needs.
- ABPI supports the European Commission’s approach regarding healthcare professionals as a primary source of information and asks the Commission to introduce a European wide communications programme to improve this particular aspect of healthcare professionals’ training.

- Effectiveness of information provision would be improved by stakeholders including the industry to present non-promotional information in a variety of formats that are widely used by, and familiar to, the public as ways to retrieve, receive and understand information (e.g. frequently asked questions, descriptions of patient journeys). Information might well go beyond the package leaflets and summary of product characteristics (SPC) and should be permitted so long as it is not promotional, is not inconsistent with the regulatory information and adds quality.
- Any future legal framework, particularly regarding the quality of that information, needs to be applicable to all information providers.
- Further consideration should be given to permitting comparisons between medicinal products as this would help patients understand their treatment and the possible changes in treatment. Comparisons indicating that one product is better than another are very likely to be viewed as advertising and would be prohibited by Directive/2001/83/EC.
- The control of information provision should be the responsibility of member states and should permit self-regulatory control as is the case with advertising. This would allow the well established existing procedures in the UK to be used and built upon avoiding unnecessary bureaucracy in line with the Commission's proposal.

## Details of our response

---

### 1. About this consultation

ABPI welcome the desire of the European Commission DG Enterprise and Industry to consult with as many stakeholders as possible on the possible legal framework. We hope that the wealth of responses the Commission is likely to receive will ensure that the Commission will take into account the many positive experiences gained at individual member state level, such as the UK. We would like to stress that harmonisation should be aimed at raising the bar in all member states to enable patients to have better and easier access to quality information about their medicines, treatments and conditions.

In the UK information provided by pharmaceutical companies to the public and patients is regulated by the ABPI Code of Practice for the Pharmaceutical Industry and the MHRA and these high standards apply to both the process and content. There are of course detailed legal requirements in the UK. The ABPI Code extends beyond the legal requirements. The effectiveness of the Code demonstrates how self regulation can contribute to ensuring high quality medicines information provision in Europe.

#### 2.1 What are the reasons for the proposal?

ABPI welcomes the European Commission's acknowledgment that patients have become more empowered and proactive regarding the treatment of their illness and urges the Commission to build upon this. A proactive patient very much reflects society at large, which is used to obtaining and searching information quickly over the internet at a touch of a button. The legal proposal envisaged by the European Commission must set a realistic framework for information available over the internet, as access to information over the internet is not entirely in the hands of the European Commission.

To assist patients in trusting internet sites, the European Commission should ensure its own health portal to be as comprehensive as possible and to ensure that the Commission takes note of good examples which are in use like the NHS Direct site in the UK, which also provides links to the Medicines Guides. More recently the Department of Health in the UK has launched NHS Choices and is currently working with a number of stakeholders, including the industry, to improve this website and to ensure that it offers a comprehensive gateway for patients looking for information.

#### Medicines Guides

An example of how this type of comprehensive information could be developed is the Medicines Information Project in the UK which provides information about individual medicines, based on the Summary of Product Characteristics, linked to information about treatment choices and the condition. The medicines information is published on behalf of the pharmaceutical industry and the treatment choice and condition information is published by NHS Direct Online.

We would encourage the Commission and others to review this resource ([www.medicines.org.uk](http://www.medicines.org.uk)) both in terms of content and in the way the partnership has

been established and the broad range of stakeholders, including the Medicines and Healthcare products Regulatory Agency (MHRA) and the Department of Health, which have been integral to the development of this valuable resource. Colleagues involved with the initiative would welcome the opportunity to meet with the Commission and share details of this project as well as user insights.

ABPI fully supports the Commission's statement that healthcare professionals should remain as they are today, a primary source of health information. In order to support this, we are asking the Commission to ensure that the completion of communication training to this effect is part of healthcare professionals standard assessment. Part of a European recognition of any foreign healthcare professionals certificate should be a successful completion of communication training focusing on information to patients.

## **2. 2 Objectives and impact assessment**

ABPI very much welcomes the objectives set out by the Commission to 'ensure the availability of good-quality, objective, reliable and non-promotional information on medicinal products'. We further fully endorse the three main objectives listed to establish a framework, maintain the ban on direct-to-consumer advertising of prescription only medicines and avoiding unnecessary bureaucracy.

Directive/2001/83/EC prohibits the advertising to the public of prescription only medicines, which we fully endorse. This prohibition is not consistently reflected in the Commission's proposal eg Sections 2.2.2 and 3.1 and we therefore ask the Commission to review those sections in particular.

## **3. Key ideas of the forthcoming proposal**

ABPI very much welcomes the Commission's intention to create a 'framework for the industry to provide certain information on their medicines to the public'. We believe that patients should have access to a multiplicity of sources of information, which includes the industry.

We would very much like to have further clarification on the point that 'information should be compatible with approved summaries of product characteristics and patient information leaflets, and it should not contradict or go beyond the key elements specified in them. Other limited medicine-related information could also be given (information about scientific studies, prevention of diseases such as vaccines, accompanying measures to medical treatments, prices). In addition, specific quality criteria should be defined and respected'.

In general we propose that pharmaceutical companies should be permitted to provide relevant information which will add quality to the patient journey and include information about the disease and its management. This might well go beyond the key elements specified in the package information leaflet (PIL) and SPC but must not conflict with their contents in any way. Overall ABPI would not like to see any restrictions on the type of information, as long as it is factual, not inconsistent with the SPC and PIL relevant, adheres to quality criteria and is not in any way promotional or advertising.

## **3.2 Scope, content and general principles of the new legal provisions**

We agree that any communication not covered by the definition of advertisement should be regarded as information.

### **3.3.1 Information passively received by citizens**

The method of dissemination of information is only one aspect that needs to be considered. Content is also a very important factor when deciding whether the material is advertising a prescription only medicine or information.

The ABPI strongly supports the current arrangements for control of advertising and proposes a similar arrangement for information provided by the pharmaceutical industry ie self-regulation backed by regulation with the responsibility at member state level. The UK position is set out in the memorandum of understanding agreed by the MHRA, ABPI and Prescription Medicines Code of Practice Authority (PMCPA). The PMCPA operates the ABPI Code at arms length from the ABPI itself. The ABPI proposal would meet the Commission's aim of avoiding unnecessary bureaucracy.

### **3.3.2 Information searched by citizens**

ABPI very much welcomes the Commission's approach of recognising industry in publishing information on relevant websites. The PMCPA already scrutinises advertising material to healthcare professionals and we would welcome scrutiny of company websites.

## **4. Quality criteria**

ABPI fully endorses the Commission's approach to defining quality criteria for information. In the UK, these are set out in the ABPI Code. Clause 20 and its supplementary information refer to the provision of information to the public and patients. However, we are unsure why 'comparisons between medicinal products should not be allowed'. It might be necessary to provide an element of comparison to allow patients to understand their treatment and possible changes in order to meet the quality standards. For example the step up and step down approach in the treatment of asthma or the treatment of type II diabetes and progression to use of insulin after oral therapy. The ABPI does not support the use of comparative claims such as one product is better than another. This would most likely be viewed as advertising and be prohibited by Directive/2001/83/EC. In the absence of reasons for this our view is that provided the information meets the quality standards which would include the need for information to be capable of substantiation it seems unnecessary to prohibit comparisons per se. It would be helpful to have further explanation on this point.

## **5. Proposed structure for monitoring and sanctions**

The UK has a long history of robust effective self regulation. Member companies of the ABPI must comply with the ABPI Code of Practice for the Pharmaceutical Industry.

In addition over fifty companies that are not members of the ABPI have also agreed to comply with the Code and accept the jurisdiction of the PMCPA. The Code includes a range of sanctions which are used if breaches are ruled including publication of detailed case reports. The comments in Section 3.3.1 above also apply here. The PMCPA would be happy to provide further details and would welcome the opportunity to discuss with the Commission the self-regulatory controls in the UK. Overall, the ABPI supports alternative 2 as laid out in the footnote to this section in the consultation document.

The ABPI would like further clarification of the role of the proposed Advisory Committee with no Comitology powers. As previously stated the implementation should be by member states using their well-established local expertise resulting from the implementation of Directive/2001/83/EC ie self-regulation backed by statutory regulation.

### **Table 6**

This does not include sufficient detail of the different types of information. These should be clearly set out in a framework. It should be noted that the important factor are both how the information is disseminated and its content. For example information that is acceptable following prescription of a product is very likely to be unacceptable if it appeared as paid for space in a daily newspaper.

The ABPI Code refers to three types of information: proactive, reference and reactive. Details are given in the supplementary information to Clause 20 of the Code.

The ABPI would be pleased to meet with the European Commission to discuss the ABPI Code and its operation or any other aspect of this response.

<p>ABPI will continue to work with patients, regulators and health professionals to enhance the means by which information about medicines is presented and provided to patients and the public in the UK to ensure that patients benefit from being fully involved and informed about diseases and treatments.</p>
---

## **Appendix – Further information can be found at**

The Medicines guides, which provides patients with access to medicines information and can be accessed at

[www.medicines.org.uk](http://www.medicines.org.uk)

Ask about Medicines provides general information about what patients might want to ask about their treatments and signposts to a whole host of relevant patient information via the Health and Medicines Information Guide.

[www.askaboutmedicines.org](http://www.askaboutmedicines.org)

Information about the ABPI Code of Practice and its operation can be found at [www.pmcpa.org.uk](http://www.pmcpa.org.uk).

### **ABPI Contact details**

Martina Bohn  
Commercial Affairs Manager  
ABPI  
12 Whitehall  
London  
SW1A 2DY  
Tel: 0044 279303477  
Email: [mbohn@abpi.org.uk](mailto:mbohn@abpi.org.uk)