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Dear Ms Narhi,

COMMENTS ON LEGAL PROPOSAL ON INFORMATION TO PATIENTS

Pharmaceutical Research and Manufacturers of America (PhRMA) is pleased to comment on your consultation document "Legal Proposal on Information to Patients".

PhRMA is the principal trade association for the innovative pharmaceutical industry in the United States. Most, if not all, of our members are active within the European Union and are directly affected by Commission policy.

While we fully understand that the Commission intends to keep the ban on advertising of prescription medicines in place, we strongly support the initiative of the Commission to prepare a legislative change, aimed at providing a better regulatory framework for information to patients. Such legislative change will be useful to ensure the availability of good quality, objective, reliable and non-promotional information on prescription-only medicines throughout the EU.

PhRMA presents the following comments on the public consultation document.

General Considerations

- PhRMA fully agrees that citizens have a right to obtain understandable, objective, high quality and non-promotional information on prescription-only medicines. This need exists for individuals, such as patients and their family members, as well as for patient organisations and other entities that have an interest in medical care and for citizens in general. The need for information is further increased by the more active role citizens, including patients, are rightfully assuming. There is also the need to ensure that patients are supported in building their skills to understand health information, obtaining health literacy.

  It is clear that pharmaceutical companies have an important role to play in that respect. We have developed, and keep developing medicines and have unique knowledge that can be very useful for the public.

- The rules governing advertising and information apply to all persons, and not only to pharmaceutical companies. This is a logical consequence of the public health considerations that are the justification of the prohibition of direct-to-consumer advertising for prescription products. It is also required under general principles of non-discrimination.

  This does not exclude that the difference between entities disseminating messages can be relevant in determining whether a specific message qualifies as advertising or information, but the legal principles should apply in the same manner to all persons.

- Relevant information on medicines cannot be compiled in one place that would provide a comprehensive overview of all relevant aspects. Making information available to the public is an organic process that involves a multitude of parties – including regulators, advisory bodies, interest groups and industry – and that is in constant flux. The regulatory framework for providing information must be flexible enough to maintain the dynamism of this process.

Finally, the Community rules on advertising medicines are becoming increasingly harmonised. The main rules were already adopted in 1992, but in practice there remained many differences between the national rules and practices. These differences were to some extent disappearing as a result of more collaboration and consultation between the national regulators, but recently the European Court of Justice held that the advertising rules in Directive 2001/83 provide a complete harmonisation in the field of advertising and expressly lists areas where Member states can adopt diverging rules (decision of 8 November 2007 in *Gintec v Verband Sozialer Wettbewerb*, Case C-374/05). This requires a fresh look at the already existing list of activities that are excluded from the definition of advertising.

Identifying Allowable Information

The key challenge is to distinguish advertising and information. This is a difficult exercise and cannot be fully addressed in an abstract manner in the rules, but will require assessment in practice, taking all the relevant circumstances into account. The procedures governing the assessment in practice, *i.e.* the monitoring procedures, will have to be sufficiently robust, practical and transparent to provide useful precedents and guidance upon which providers of information can subsequently rely when structuring information activities.

The following approach is suggested for structuring the new rules:

- The definition of advertising in Article 86 (1) of Directive 2001/83 is open ended. It is also de facto impossible to provide a comprehensive definition.

- There is no need to first distinguish between "advertising" and "information" and then set standards for information, which logically results in the possibility of improper information (that does not meet the relevant standards) that is not advertising. It is more efficient to exclude from advertising information that conforms to the relevant standards.

- Article 86 (2) already excludes certain activities from the advertising rules, such as product labelling and package leaflets, responses to specific questions, trade catalogues and price lists, etc. These exclusions have not given rise to significant problems and should be maintained. The list should, however, be updated in light of the ECJ decision in *Gintec* and concrete recommendations are provided below. Because of their specific nature, there is also no need to apply the standards for "information to patients" to these activities. Obviously, for instance, a response to a specific question can contain much more information (provided the response does not go beyond the question asked) than a general piece of information in a magazine can be.

- It is important to recognise that because of these elements the concept of advertising under Directive 2001/83 is different from the broader concept of advertising under Directive 2006/114 concerning misleading and comparative advertising. This is, for instance, illustrated by Case C-112/99 *Toshiba v Katun* where trade catalogues for photocopy products -- of a similar nature to those excluded under the third indent of Article 86 (2) for medicines – were reviewed under the predecessor of Directive 2006/114.

These elements are best implemented by amending Article 86 (2) and to adopt a new article 100a.

Standards for Information

The key standard for information to patients is that it must be balanced, accurate and not misleading and must present the medicinal product objectively and without exaggerating its properties

There is no need to specifically restrict information to patients to information that is compatible with the approved summary of product characteristics and patient leaflet. Useful additional information can include general disease management information, details on and assistance with therapy compliance, general dietary recommendations, pricing and reimbursement information, ongoing clinical research, etc. In certain circumstances, the additional useful information may reflect results of clinical trials that are not yet taken into account in the approved SmPC and leaflet, but this can only be done when the information is "balanced, accurate and not misleading" and "presents the medicinal product objectively and without exaggerating its properties."

The non-promotional nature of information should take into account all the relevant circumstances. Information sought by the citizen ("pull") can be presumed to be non-promotional if it complies with the general principles governing non-promotional information. Unsolicited information ("push"), however, can also be non-promotional and can play an important role, such as disease awareness information, therapeutic compliance guidance, information on patient support programmes, etc. It could indeed be useful to require in "pushed" information a reference to a place (for instance the EMEA website) where the approved SmPC and patient leaflet can be consulted. This can result from the general requirement of "balance" but the requirement, and details on when and how it applies, are best laid down in an implementing code of conduct or guidelines.

Comparative statements may in many cases not be appropriate in information to patients, but should not be entirely excluded. Again, it is best to address this in a code of conduct or guidelines.

Finally, it should be possible for pharmaceutical companies to disseminate information on their websites and through other media that specifically responds to statements made by third parties on their products.

Monitoring

The monitoring aspect of the regime for information to patients should not be considered separately from the development of concrete standards. The experience in various Member States has shown that the quality of a regime – and in particular its clarity, predictability, and reasonableness, and an adequate reflection of practical needs and technological developments – is only possible when there is a constant interaction between the monitoring system and the development of the rules, in particular in the form of guidelines.

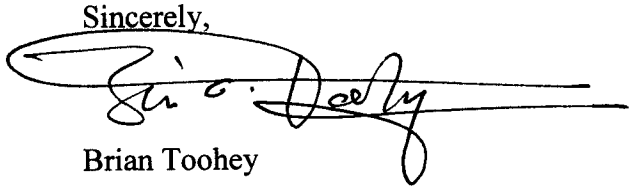
In that light, a self regulatory system should be stimulated because it provides the best guarantee for an effective mechanism. It should, of course, be backed up with powers of regulatory authorities to intervene when needed.

Again, this would require significant details that cannot be addressed in the text of Directive 2001/83. In addition, as there will in many instances be a need for a Community process, the realisation of the new monitoring regime will probably require time.

In addition, it is submitted that a Community advisory body should be a separate body, specifically dedicated to medicines information activities, and should include representatives of interested parties in an equal composition. The Pharmaceutical Committee has a very wide scope of responsibilities[1] and is composed of a representative of each Member State plus the Commission chair person.

Thank you for considering our comments. We look forward to continued dialogue on this very important initiative and hope for a Commission proposal by the end of this year. We would be pleased to propose draft language that reflects our comments.

Sincerely,



Brian Toohey

[1] Examination of "any question relating to the application of the [Directives on medicines]" and "any other question in the field of ... medicinal products" (Art. 2 of Directive 75/220).