European Research into Consumer Affairs

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Public consultation on the Legal Proposal on Information to Patients

European Research into Consumer Affairs (ERICA), founded in 1978, undertakes research leading to action for all European consumers, but particularly those who are disadvantaged. It sets out to improve life for Europe's more vulnerable consumers by identifying key problems, researching them and proposing solutions. Its brief includes healthcare and it has previously contributed to consultations regarding the advertising of pharmaceutical products.

General points

ERICA welcomes the Commission's initiative in introducing this public consultation on its Legal Proposal on Information to Patients. But it notes that the consultation derives from DG Enterprise and Industry rather than from DG SANCO. It would have been preferable for it to be a joint consultation so that health could be seen to be the main emphasis. A consultation from DG Enterprise and Industry alone could potentially attract a distorted response, with reactions from the pharmaceutical industry dominating opinions.

ERICA points out that any information engendered by pharmaceutical companies will inevitably relate to branded products. What is to be the role here for the cheaper and frequently equally effective generic drugs (e.g. statins in the UK), which many doctors are urged by their governments to supply?

Nevertheless, ERICA endorses the following points:

- It agrees with the need to deal with variability and inequality of access to information that exists among the Member States. Harmonisation of practices and provision of information is essential.
- It is vital that healthcare professionals, well-trained and updated, must remain the primary source of health information.
- It is equally vital that the interests of patients must be put first.
- It recognises that a clear distinction between advertising and information on prescription drugs must be maintained, with advertising of any kind remaining banned in the EU.

It stresses the importance of objective, non-promotional **easy to read** information, enabling patients to make informed decisions about the best treatment for themselves after having weighed up the risks and benefits.

It emphasises the importance of a transparent structure for continuous monitoring of the quality of patient information.

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Specific Comments (using the consultation document's paragraph numbers)

3. Scope, content and general principles

ERICA notes that it is the intention of the Commission to allow pharmaceutical companies greater public access in the provision of their information. The constraints on this information are that it must be compatible with approved summaries and Patient Information Leaflets (PILs).

3.2. At present the only obligatory way for pharmaceutical companies to be in direct contact with patients is by PILs appearing with prescription medicines. The Commission regards these as one of the base lines for factual communication if further information media are to be developed. ERICA points out that the present leaflets still have many shortcomings as far as patients are concerned, particularly as regards readability, irrelevance of introductory paragraphs, and anxieties aroused by the often unclassified listing of side effects.

The revised EU guidelines should be monitored more closely and if necessary tightened. Provision also needs to be made to give information to patients who receive medication from pharmacists who are in receipt of bulk supplies.

ERICA would like to see an independent evaluation of the information leaflets already produced by pharmaceutical companies.

3.3.1. ERICA is concerned about the unsupervised transmission of passive information proposed for patients on prescription-only medicines. Information handed out by and discussed with a health professional is acceptable, but TV and radio information on a single branded product (as opposed to general information e.g. on vaccination) is not. Vulnerable, gullible, semi-literate viewers and listeners, unassisted and unadvised in the security and comfort of their own homes, are capable of being directed and even manipulated by what they see or hear as the unquestioned voice of authority. There is no comparison with alternative drugs, and there could be consequent pressure on doctors to prescribe the one seen on TV or heard about on the radio.

It would be helpful to know if printed material is to appear openly ascribed to the pharmaceutical company, or (for example) to a doctor acting on its behalf. What sort of “mechanism” is intended to supervise this?

3.3.2. Active as well as passive patients can fall victim to misinformation. A new generation of patients seeks out information, particularly from internet websites some of which additionally induce patients to buy potentially inappropriate medication. While it is impossible to control such sites originating in the United States, the EU must be more vigilant over use of the internet within its own boundaries. Since pharmaceutical companies operate in different Member States, it will be difficult for **national** co-regulatory bodies to monitor a harmonised input.

3.3.3. Patients are known to welcome the opportunity of direct contact with pharmaceutical companies whose address is included in the PILs. Replies must be monitored to see if they contain undue promotional material. But the suggested

rationale based on complaints is too narrow. Reasons for refusing to give information should also be checked – for example, those of a company which withheld information from the patient on side effects.

4. Quality criteria

The criteria outlined by the Commission are sound, though once again ERICA would add the word “understandable” to the list. Certainly, no company must be able to make comparisons. But by the same token patients do need Which?-type advice in order to be able to compare one product with another so that they can make an informed choice.

5. Proposed structure

The Commission suggests three levels of possible enforcement. It would have been helpful if the structural diagram were followed by a text which kept the same order.

a) The Commission suggests stakeholder membership of a national co-regulatory body. In order to achieve a broad and balanced input, ERICA suggests the inclusion of consumer organisations in addition to wholly independent patients organisations. Patients organisations by their very nature are strong lobbyists for particular causes and can form alliances with drug companies which provide funding. They therefore could be inclined to bias.

b) ERICA questions what sort of meaningful sanctions could be applied by national competent authorities to pharmaceutical companies.

c) The text mentions an Advisory Committee at EU level, and the potential role of the existing Pharmaceutical Committee. ERICA would like to know about the breadth of membership and independence of this Committee. It suggests that the inclusion of the BEUC, the European Consumers' Organisation, would introduce greater certainty of independence.

The same paragraph mentions the possible role of the EMEA but suggests its contribution should not have any further role as no scientific assessment of information will be necessary. In view of the doubts cast (February 2008) over the inadequacy of information (including clinical trials) of anti-depressants, ERICA believes assessment of information may sometimes be necessary.

ERICA is not in favour of regulation by pharmaceutical companies on a self-regulatory basis and prefers the option of national competent authorities supported by adequate resources for this additional role.