



Commission public consultation on the key ideas of a legal proposal on information to patients

ECPC Response

ECPC is extremely disappointed with the Commission's current document on outlining the legal proposal on information to patients which does not adequately address the needs of patients, nor meet the Commission's stated policy objectives.

Firstly, the advertising/information distinction is particularly unsatisfactory. In Article 86 of Directive 2001/83/EC, advertising is defined as "any form of...inducement designed to promote the prescription, supply, sale or consumption of medicinal products." This seems a reasonable statement, but it is not made clear how it could be practically applied in any given circumstance.

The Commission makes an attempt with regards to TV and Radio, apparently suggesting that the key lies in the content of the programme with which the communication is linked. Advertising consists of "short slots, not linked to the content of the programme" whereas information is linked with "programmes with factual content." This is wholly artificial and incongruous with the Directive definition. Why should the length of slot and linkage with the programme necessarily prove/disprove commercial intent?

The result is that it will be impossible to prove whether a particular TV or radio broadcast amounts to advertising or information. But crucially, because "information" is defined in the negative, as that which is not advertising, the communication will be assumed to be information. The burden of proof lies on those making complaints to show that it falls into the category of advertising, likely an impossible and/or expensive task. Subliminal messages can easily be hidden in so-called "factual" programmes.

Secondly, the monitoring and enforcement system is bureaucratic and unworkable. TV and radio information would have to be approved ex-ante and specially monitored for any "hidden" or "subliminal messages". The proposal contains important alternative suggestions such as regulation by the medicines regulatory authority or self-regulation but for some reason these are relegated to the footnotes.

Finally, ECPC is concerned that the mechanism outlined would not increase harmonisation and access to patient information across all EU Member States. The last Commission report showed that there are already large inequalities in the availability of statutorily permitted information across Member States. Some countries, such as Germany, consider the package leaflet to be advertising if it is

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outside the package. But why should a patient not be able to download the package leaflet from their Medicines Agency website if it were made available? It is in no way clear how this proposal would serve patients with better information in their own language in all EU member states.

ECPC strongly supports the attempt to provide more information to patients. Indeed it is a right and cancer patients' lives may depend on what information they have. But we believe that it is impossible to rely on an advertising/information distinction. Therefore we go back to our suggestion to leave the Advertising Directive untouched and instead come forward with a proposal for an **improved patient information leaflet**. Patients are better served by a push/pull separation which applies to the internet. Cancer patients would like to have the same information as their doctors on a "pull" basis. Material which is passively thrust upon citizens should be banned whilst that which is actively searched for should be permitted with appropriate safeguards in place. However, TV and radio communication, traditionally very powerful mediums for advertising, should remain banned.

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Nothing About Us Without Us

The European Cancer Patient Coalition (ECPC) was founded in September 2003 with the aim of giving cancer patients a voice in shaping the European Union's policies that impact on cancer care. ECPC's objectives are:

- Promoting the fundamental rights of European cancer patients
- Increasing cancer patients' representation and influence at the highest level of decision making Europe-wide
- Help patients obtain timely access to appropriate and accurate prevention advice, medical diagnosis, treatment and care
- Promoting the advancement of cancer research
- Empower patients to become true partners in the healthcare system

Currently, **ECPC** has over 250 members from most EU Member States and represents patients with cancers of the commonest sites such as lung, breast, prostate and colorectal cancer to the rarer cancers such as multiple myeloma, chronic myeloid leukaemia as well as childhood cancers

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