

PUBLIC CONSULTATION
LEGAL PROPOSAL ON INFORMATION TO PATIENTS
EUROPEAN COMMISSION
2008

ESMO COMMENTS

ESMO (European Society for Medical Oncology) is a highly qualified professional, scientific and educational society. With a worldwide membership since 1975, ESMO has continuously expanded its mission, aiming to create a wider community of professionals providing optimal care to all cancer patients.

ESMO strives to develop solutions, actions, initiatives that can help fighting against cancer and improving patients' quality of life.

ESMO participates to the improvement of the education of health professionals and the public. ESMO is not only a relevant place for health professionals but offers also a forum for a global community where patients and their families are significantly present.

ESMO (European Society for Medical Oncology) would like to thank the European Commission for the opportunity given to contribute to the public consultation process related to the legal proposal on information to patients.

ESMO position includes:

- general comments
- specific comments
- conclusions

1. **General comments**

ESMO thinks that the information issue is complex due to the great number of stakeholders and the evolution of technologies and techniques as described in the “Communication from the Commission to the European Parliament and the Council concerning the report on current practice with regard to provision of information to patients on medicinal products”.

ESMO agrees, with the European Commission, that the issue of patient information is of growing importance with the new paradigm where patients are more empowered and become proactive partners of the health professionals to get better output.

ESMO reckons also that the quality of information and the access is still very variable in Europe and that a legal framework proposing rules that harmonize the practices on information provision to patients could help.

Nevertheless ESMO considers that, whatever the proposals can be, the new legal framework must mainly meet patients’ expectations and reassure that the dialogue between health professionals and patients remains the central point in the patient journey and cannot simply be replaced by the provision of information on medicinal products. Therefore ESMO stresses the necessity for health professionals to be educated and enabled to communicate with patients to provide them with tailored, timely and up-to-date information. This is particularly necessary for cancer acute disease and its chronic characteristics.

In some extend, the consultation does not really focus on this consideration.

According to ESMO, information on medicinal products is one piece in the information global picture and cannot be isolated from any other kind of information. Indeed, patients are keen to get information along the patient journey about their health condition, the proposed medical procedures, potential risks and benefits of treatment, alternatives....

The proposal does not consider the variety of information sources, focusing exclusively on pharmaceutical information.

ESMO considers also that proposing numerous and various types of actions by providers (advertising, pushed information, information searched by citizens, answering on requested) could possibly create more complexity for patients as the proposed procedures for monitoring, the competent authorities and bodies, the sanctions and responsibilities are not the same and will , once again, vary amongst the Member States.

Finally ESMO is afraid that patients will be lost in a labyrinth of information focusing exclusively on medicinal products with a certain degree of complexity while patients need to get an easy access to high quality health information and probably a focal information point for all kind of health information. This has not been considered as a possible option by the European Commission's proposal.

2. Specific comments

About information passively received by patients

This paragraph making possible for pharmaceutical companies to disseminate information on prescription-only medicines through television and radio programmes, through printed material actively distributed, through information in printed media or through audiovisual and written material provided to patients by healthcare professionals sounds a bit confusing considering the ban on public advertising.

About information searched by citizens

This proposal does not really face a main problem of access to Internet and computer literacy that is often synonym of inequalities between European citizens.

Proposing validations mechanisms by national co-regulatory bodies has a cost. It is unsure for ESMO that all EU member States would be able to budget this new national competence.

About answering requests from citizens

This proposal and the complaint mechanisms does not seem realistic and is probably not feasible. It is unclear who will treat the complaints.

About the quality criteria

ESMO welcomes the incorporation of the quality criteria.

About the proposed structure for monitoring and sanctions

The structure of enforcement appeals a few comments. Subsidiarity will limit the powers and competences of the EU advisory committee while the national competent bodies will adopt Codes of conduct that are variable; what will not foster the equality between European citizens.

3. Conclusions

While we recognize that a European legal framework can contribute to improve patients' information, ESMO considers that patients' concerns and benefit are not really met by the current proposal focusing exclusively on the role pharmaceutical industry could play as the main information provider.

Besides, the proposals have a very limited effect as the structure for monitoring and assessment will mainly be a national competence with once again a possibly high degree of variety amongst Member States.

Finally, ESMO deeply regrets that the proposal does not promote a comprehensive approach including health professionals.