



European Society
for Medical Oncology

CONSULTATION REGARDING DRAFT REPORT ON CURRENT PRACTICE WITH REGARD TO
PROVISION OF INFORMATION TO PATIENTS ON MEDICINAL PRODUCTS
IN ACCORDANCE WITH ART 88A OF DIRECTIVE 2001/83/EC AS AMENDED BY DIRECTIVE
2004/27/EC ON THE COMMUNITY CODE RELATING TO
MEDICINAL PRODUCTS FOR HUMAN USE

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 consultation process related to the Draft report on current practice with regard to the provision of information to patients on medicinal products.

The document includes:

1. Global assessment of the draft report
2. General comments
3. Suggestions

1. Global assessment of the draft report

ESMO believes that the draft report represents a useful compilation of what exists at European Union level and Member States level.

ESMO considers that the present document provides with a clear and comprehensive picture of the political and legal frameworks.

ESMO reckons that the current practices, the patients' needs and the role of different stakeholders have been all taken into consideration by the authors of the document.

2. 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 draft report.

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.

3. Suggestions

About information extend

- Patients' information should be placed in the context of the involvement of patients in their care decisions developing into a growing movement of recognition of patients' rights in Europe (including right to information). This trend originates in the recognition of fundamental values and major changes in the relationships between healthcare providers and patients.
- ESMO considers that 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...
- ESMO is also convinced 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 information. This is particularly necessary for cancer acute disease and its chronic characteristics.
- ESMO points out that information on medicinal products, any other kind of information related to health status and the vital dialogue between patients and health professionals are all complementary and crucial elements.
- ESMO stresses the necessity to deliver also information to healthy people to organize efficiently prevention of illness.

- ESMO is in favour of the creation of guidelines, standards and criteria to assess quality information and deliver evidence-base information on medicinal products.

About the European institutions and the Member States

- ESMO figures out that a better cohesion of the European Union information mechanisms could be a benefit for patients and health professionals to have a facilitated access to information.
- ESMO stands for the creation of focal information points on medicinal products in the Member States delivering update, timely, good-quality, objective, reliable and non promotional information on medicinal products.

About the different stakeholders

- ESMO pleads for the recognition in the draft report of the relevant role of the non for profit scientific associations, professional societies and foundations which can help the global community of health actors and patients by providing information on different supports.

About Internet

- ESMO considers that Internet offers many advantages by putting resources at fingertips round the clock. Nevertheless ESMO agrees that many efforts must be done in terms of access to Internet, education of users, assessment of information and the language. Internet should in no way replace other traditional information supports.

About the future strategy

- ESMO deeply regrets that, besides the statements of the draft report, there is no proposal for a global strategy while article 88a provides that "the Commission shall, if appropriate, put forward proposals setting out an information strategy to ensure good-quality, objective, reliable and non promotional information on medicinal products and other treatments and shall address the question on information source's liability".