COMMUNICATION FROM THE EUROPEAN COMMISSION
'Consultation regarding Community action on health services'

ESMO Position

ESMO, the 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 Community action on health services.

ESMO's reply is composed of an introduction/ background as understood by ESMO, a summary of ESMO's position, replies to the EC questions and some information about ESMO and its mission.

I. Introduction / Background

High quality health services are a priority for European citizens and the rights to healthcare are recognized in the charter of Fundamental Rights of the EU.

In its 2005 Report on Patient mobility and Healthcare developments in the EU, the European Parliament called for the Commission to act on a wide range of issues related to patient mobility and wider cooperation between health systems.

At the health Council of 1 June 2006, ministers adopted a "statement of common values and principles in EU health systems" which underlined the importance of "protecting the values and principles that underpin health systems in the EU "and called for action:
"ensuring clarity for European citizens about their rights and entitlements when they move from one EU Member States to another and enshrining these values and principles in a legal framework in order to ensure legal certainty"

In its 2007 annual policy strategy, the European Commission undertook to develop a community framework for safe, high quality and efficient health services, by reinforcing cooperation between Member States and providing certainty over the application of Community law to health services and healthcare.

As a matter of principle, any Community action must respect the principles already established by the Court in this area as well as other existing Community provisions and the basic principles underpinning European health systems, including equity, solidarity and universality.

The Commission considers the Community action should be founded on two pillars:

- Legal certainty, which citizens as well as national and local health actors currently feel lack of. There is a need to address the wider application of the European Court of Justice Rulings regarding Treaty provisions on free movement of patients, professionals and health services. This focuses in particular on cross-border care, but cross-border care has consequences for all health services, whether provided across borders or not;

- And support for Member States in areas where European action can add value to their national actions on health services. This should enable those responsible for health systems (including social security

institutions) to have a clear framework of Community law within which to operate and take advantage of cooperation between health systems where helpful in providing safe, high-quality and efficient health services.

II. ESMO's position on the "Community action on health services": summary

Taking into consideration:

- That governments are responsible for ensuring the quality and safety of healthcare provided to their citizens and patients,
- That Member States face the same challenges (demographic ageing, accessibility of care for all, request for high quality care, rapid development in medical sciences/technologies, rising public & patients expectations, need to ensure long term financial sustainability of care) , and therefore recognize the need for action at EU level that will bring benefits to national health systems and patients (like the open method of coordination to share best practices and the high level group on health care services and medical care to develop concrete actions),
- That Community action should in no way be a step back from what already exists and that any Community action must respect the principles already established by the Court in this area. The rights acquired today should in no way be put into question, but, to some extent, the rights of patients to seek medical treatments abroad should serve as an incentive for the Member States to improve their own health care system and structure (ensuring access to quality treatment in every country will reduce the need to cross the border)
- That since 1998, case law is clear and need enforcement by the Member States.
- That for the purpose of this document the European Society for Medical Oncology will focus on cancer and the cases of cancer patients and will therefore mainly address the issue of treatment which are planed after diagnosis (and not the case of unexpected acute disease happening when the patient is abroad)
- That in general, cancer patients prefer to be treated close to home, but in some cases they are in need to seek healthcare abroad (see few examples given below).

And in order to

- Keep the interests/benefits of all European patients in the middle of the debate ("a patient centred approach")
- share values and principles for health services on which citizens can rely throughout the EU
- support Member States which have to regulate and plan their own systems without creating unjustified barriers to free movement;
- balance patient's rights to cross-border healthcare with financial sustainability of Member States;
- ensure effective financial compensation measures are in place;
- help identifying, comparing or choosing between providers in other countries;
- contain the likely impact of cross-border healthcare on social services and long-term care.

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ESMO recommends the following:

1. Each Member State should analyze its current "health" structure and establish quality criteria according to which they select and accredit their own centres of reference, handling in the most cost/effective way the issue of economy of scale (creating networks between their centre(s) of reference and local units, ensuring that after a short stay in the centre of reference for a specific

medical act, the patient can be treated close to home according to therapeutic protocols established by the centre of reference).

Ensuring quality and safety of healthcare provided to citizens requires indeed well organized hospitals and departments in hospitals working according to defined quality criteria with qualified physicians/recognized specialties (complying with EU standards).

Remark:
-In the field of oncology, Medical oncology which exists in 17 Member States needs urgently to be recognized at European level.
-In the field of cancer, Governments should accredit their comprehensive cancer centres where multidisciplinary teams of highly qualified specialists should be available to treat according to strict quality criteria the different tumour types.

EU role at this level:

- Everything should be based on "quality criteria/assurance" (education of health professionals, infrastructures, diagnosis, treatments, care etc). Using as a basis to define them "European quality criteria" defined according to agreed recommendations, the state of the art and evidence based medicine (with the help of learned based societies, like ESMO in the field of oncology), will help sharing best practices at European level and will progressively help the different EU Member States to align their standards on "European quality standards and guidelines models".
- Networks between the centres of reference of the different EU Member States should be created at EU level. A European database including the name of the different centres of reference (audited by appointed European experts) in the different countries should be created and made accessible in order to disseminate the information throughout Europe.
- High education and CME of professionals has to be developed in countries (according to standards recognised at EU level and supported by the majority of EU member States/ "recognition of professional qualifications") in order to ensure a good follow-up treatment in all structures/hospitals/units.

9) In case, a Member state doesn't have its own centre of reference to treat the patient according to the state of the art, the member state should accept to send the patient abroad in a centre of reference of its choice (selected on the basis of medical criteria in the European database by 2 qualified physicians. These physicians can belong to an academic setting or to a public or private hospital) and in this case should accept reimbursing the cost of the treatment in the host country (incentive for some member states to improve their national structure to avoid having to reimburse more expensive treatments abroad).

NB: If the patient wants to choose him/herself, he/she must accept to pay the costs

- It has to be underlined that this happens already regularly:

1. Belgium was sending regularly cancer patients –in case of melanoma/sarcoma- for limb perfusion (to avoid limb amputation) to the Netherlands (reimbursing the Netherlands for the cost of the treatment).
2. Cases of patients suffering from a cancer located close to the "optic chiasm" and who are sent abroad to get access to the proton beam technique.
3. Cyprus is spending 15.000.000 euros/year to send (to Israel or the UK) cancer patients who require a bone marrow transplant, or for patients who require to get access to PET scan (the acquisition of a PET scan in Cyprus today doesn't make sense because nobody is trained to use it properly).

- Cases like these ones may remain perfectly logical if we keep in mind the concept of economy of scale, or rarity of a disease or lack of education for some specific techniques. But this shouldn't become regular practice otherwise the health services will not be properly developed in some member states.

  Remarks:
  -In some cases Member States might consider an agreement with a "border" country able to offer the "state of the art" treatment or part of it to those patients living close to the border.
  -In some cases (to be decided with the medical team) the patient should be authorized to participate in a clinical trial abroad (ideally governments should be able to progressively be involved in clinical trials. This could only improve the quality of national care). In these cases, the home country should probably be ready to pay the costs not covered by the Clinical Trial sponsor.

3. Since it is the home country which chooses the centre of reference in the host country, there must be a shared responsibility in case of problem (not due to malpractice). For example the home country should take care of the patient once he/she is back in his/her country and is for example suffering from extravasion or neutropenic fever due to chemotherapy.
In any case, the patient should be informed (and sign an informed consent) that there can be some risks linked to out of country treatment.

4. Patients should have access to a 2nd opinion. In this case, the medical team should select one of the centres of reference listed in the European database. In case the patient prefers to select him/herself the centre of reference he/she must be ready to cover the costs.
Remark: Telemedicine could play an important role in the context of 2nd opinion.

III. ESMO reply to the Questions from the Commission

1) What is the current impact (local, regional, national) of cross-border healthcare on accessibility, quality and financial sustainability of healthcare systems, and how might this evolve?

Current impact
The current impact is unknown, but by any means must be small.
Today, in the field of cancer, there are different known cases of cross-border care in some specific circumstances, for example when a specific technique is required and not available in the home country (limb perfusion, proton beam for cancer located close to the optic chiasm, PT scan, bone marrow transplant, etc).

How might this evolve?
Cross-border healthcare might increase if Member States do not develop in an appropriate way their own healthcare system and structure and therefore are not able to provide their patients with quality care. Member States should be able to ensure the best possible health services and keep the option of sending patients abroad only in specific cases for specific diseases, specific medical treatment or diagnosis and experimental treatment cases.

In terms of accessibility: the increase of cross border care may decrease the access to treatment of the host country citizens.

In terms of quality: an increased / unlimited cross-border care system would not help the home country to improve the quality of its own health services (no incentive if anyway the patient considers he/she will get better treatment abroad). The level of expertise of the professionals in the home country will decrease also, or they may be willing to delocalise their practice to be in a more motivating environment.

In terms of financial sustainability: if the reimbursement doesn't correspond to the real cost of the care in the host country, this will not be financially sustainable for the host country. Moreover, the home country will probably not be able to justify investments in its own healthcare system (to maintain a certain level of health services) if citizens/patients are more and more going abroad.

2) What specific legal clarification and what practical information is required by whom (e.g.; authorities, purchasers, providers, patients) to enable safe, high quality and efficient cross-border healthcare?

The model described in the summary (see: II ; ESMO's position on the "Community action Health services": summary) is entirely based on "quality criteria/ compliance and audit" done first by each government in their own country and based (for guidance) on European standards/models. On the basis of these criteria, Centres of Reference are accredited by their governments and should be audited by European experts groups in order to be listed on the European database which will be made available to disseminate the information.

In this model, it is up to the Member State which cannot offer the state of the art treatment (or diagnosis) for a specific patient, to send the patient abroad in a centre of reference of its choice (selected on the basis of medical criteria in the European database by 2 qualified physicians). The European database which only lists the centres accredited by national governments and audited by the European expert groups offers a guarantee of quality.

Obviously, in order to guarantee the overall quality of treatments, the quality of education of healthcare professionals has also to be defined (in addition to quality criteria regarding structures, and best clinical practices). It is therefore important to take into consideration the recognition of medical specialties throughout Europe as a pre-requisite for acceptable high quality care in all Member States.

Remark: ESMO is for the time being working to achieve the recognition of Medical oncology (which exists in 17 Member States) with a minimum training requirement of 5 years. ESMO has also developed a "global core curriculum", is very active in the education field and recertification process of professionals in oncology and has started a process of accrediting "designated centres of integrated oncology and palliative care"(An Oncology Accreditation Committee has been created to oversee and provide guidelines for the professional and institutional accreditation programs in medical oncology).

3) Which issues (e.g. clinical oversight, financial responsibility) should be the responsibility of the authorities of which country?
4) Who should be responsible for ensuring the safety in the case of cross-border healthcare? If the patients suffer harm, how should redress for patients be ensured?

From a general point of view, governments are responsible for ensuring the quality and the safety of health care provided to patients. They therefore have to organize their own "health services structure" in organizing their hospital and hospital departments with qualified physicians. (Remark : There are huge differences in cancer treatment outcomes between the different EU Member States, but also within the same Member State, between different hospitals!)

In case of cross border care, in the model presented in the summary, the home country selects the centre of reference of a host country (NB: the patient remains free of course to select another centre and/or country, at his/her own expenses). In this case the responsibility for ensuring the quality and safety of health care provided to the patient should be a shared responsibility (except in case of malpractice) between the Governments of the 2 Member States. For example the home country should take care of the patient once he/she is back in his/her country and is for example suffering from extravasion or neutropenic fever due to chemotherapy.

Malpractice is the responsibility of the treating physician. To minimize the risk of error and harm to patients there is a need to ensure highly qualified expert physicians and care professionals.

In any case, the patient should always be properly informed that there may be some risks related to the travel between 2 countries/cross border cares. The patient should sign an informed consent confirming he is aware of these risks (to be defined on a case by case basis) linked to "out of country treatment".

The home country is responsible for ensuring that its structure and the training of its professionals are such that it can ensure the quality of the follow-up treatment (when needed/particularly needed for long term diseases). The establishment of a European network of national centres of references and of national networks between centre(s) of reference and local unit/hospital will facilitate the follow-up treatment according to agreed protocols.

5) What action is needed to ensure that treating patients from other Member States is compatible with the provision of balanced medical and hospital services accessible to all?

Cross border care is not a solution per se for improving health services at EU level. The possibility to get access to care abroad should be used to stimulate national governments to invest in their healthcare system and structure (as described in the summary). This is only in case a Member State cannot treat (or diagnose, etc) according to the state of the art that the Member State should accept to send the patient abroad and therefore to reimburse the cost of the treatment in the host country.

"Unlimited" mobility in direction of certain member states would create unbalanced situation in the accessibility of medical and hospital services for the citizens of these Member States

6) Are there further issues to be addressed in the specific context of health services regarding movement of health professionals or establishment of healthcare providers not already addressed by Community legislation?

7) Are there any other issues where legal certainty should also be improved in the context of each specific health or social protection system? In particular, what improvements do stakeholders directly involved in receiving patients from other member states – such as healthcare providers and social security institutions – suggest in order facilitating cross-border healthcare?

There is a need to ensure that all health professionals are well qualified, according to standards recognized at EU level (supported by the majority of Member States, e.g. "recognition of professional qualifications"):

- to ensure high quality of care,
- to ensure reliability of patient's medical data in case of cross border care (to be sure about the quality and the results of all exams and diagnosis tests already performed, and to avoid the need to start again/duplicate)
- to allow the mobility of health professionals.

In the field of cancer it is extremely important to note that despite the existence of "medical oncology" as an independent specialty in 17 Member States, the specialty is not yet recognized at EU level (not listed in the Doctor's Directive). ESMO is working to achieve this recognition since today All the specialists in oncology are convinced that the current developments in cancer care require more and more a multidisciplinary approach, and the role of medical oncologist in the multidisciplinary team is pivotal..

"The establishment of multidisciplinary teams, with experts in surgical oncology, radiotherapy and medical oncology is needed to provide the optimal treatment since:

- The management of cancer patients has undergone major changes over the last couple of decades thanks to a steady increase in the knowledge of the biology of the disease and a concomitant better treatment strategy, using both local therapy, such as surgery and radiotherapy, combined with medical treatment.
- Simultaneously, new, more complex techniques have been developed within surgery, radiotherapy and also medical oncology with a large number of new drugs, including cytostatic agents, monoclonal

antibodies, vaccines, hormones, etc, all of which require a very detailed knowledge of the management of cancer patients.
- The development of new drugs with new mechanisms of action that may be closely related to the molecular biology of the tumour and the increasing importance of pharmacogenomic considerations in the optimization of treatment require a very specific education in order to ensure an extensive knowledge of drugs handling.

In these multidisciplinary teams:

- The medical oncologist's specialist role is to support the development of efficient drugs and to prescribe appropriate drug related treatment regimens (including chemotherapy, hormonal therapy, newly developed treatments such as immunotherapy, targeted treatments) and to ensure the management of associated treatment toxicity.
- The medical oncologist works very much as part of the integrated, multidisciplinary team and has a pivotal role in liaising with primary care, clinical oncologists, palliative care support, and other medical and surgical specialists in the cancer centre and unit"

8) In what ways should European actions help support the health systems of the Member States and the different actors within them? Are there areas not identified above?

1° As said earlier, Europe has a major role to play in sharing best practices by developing Quality criteria for structure, procedures, diagnosis, treatments, care, education of professionals, etc which should serve as guidelines for the development of those used by the Member States, hoping that progressively we will have a more or less standardized situation throughout Europe.

2° Europe should listen to and consult well established and recognized learned based societies, the mission of which is often to improve knowledge and education, to disseminate information, to set criteria, etc. Coordinating new initiatives with the work already done by these European societies would avoid duplication and save time and money.

3° Europe has a major role to play in raising awareness of the existing health care gaps across the European Union and particularly in the new Member States and should help these Member States to get access (under the requested conditions) to the EU structural funds in order to ensure improvement in health care and help reducing the health divide between old and new Member States.

4° The creation of a network for experimental oncology (translational research and clinical trials) and the creation of a network for second opinion providers (the use of telemedicine could be extremely helpful in this context) are also important steps to improve the care of European cancer patients

9) What tools would be appropriate to tackle the different issues related to health services at EU level ? What issues should be addressed through Community legislation and what through non-legislative means?

1° Since 1998, case law is clear and need enforcement by Member States.
2° As the Member States and the European Union are willing to provide their citizens with high quality health services, it would be appropriate to issue European recommendations concerning the minimum health care services every Member States should offer to its citizens, including the quality criteria for structure, procedures, diagnosis, treatments, care and education of health professionals.

IV/ About the European Society for medical oncology

Founded in 1975 as the Société de Médicine Interne Cancérologique, ESMO took on its present name in 1980, when it transformed into a pan-European organization that established itself as a leading and highly respected institution in the field of oncology. ESMO is the leading European professional society of medical oncologists, welcomes other related specialties, and has a worldwide membership from over 100 countries. ESMO's flagship journal, *Annals of Oncology*, ranks among the top five clinical oncology journals.

The major focus of all ESMO activities is to improve cancer prevention and early diagnosis of cancer, as well as diagnosis, treatment, and follow-up care of cancer patients. In keeping with its mission to embrace patients' needs, an open dialogue between patients and physicians has led to the forging of a patient-physician partnership, to which patients bring their needs and direct experiences, while physicians contribute with evidence-based science, in a united effort to improve healthcare services throughout Europe.

Current developments in oncology indicate the need for treatment by multidisciplinary teams. To this end, ESMO offers multidisciplinary programs which foster collaboration between different disciplines within the Society, such as medical oncology, radiation oncology, surgical oncology, pediatric oncology, basic research, oncology pharmacy and oncology nursing.

ESMO's multidisciplinary vision has also led to the forging of strategic partnerships with the other oncology societies, associations in specific fields and cancer organizations both in Europe and around the world. ESMO is a competent, credible partner and consulting Society that works with numerous organizations, including the European Medicines Agency (EMEA), the European Union (EU), and the World Health Organization (WHO). ESMO has also actively been strengthening working relationships with some of the major national and regional oncology societies around the world with initiatives such as reciprocal membership, joint projects and exchange programs.

As part of its global vision and strategy ESMO has become more active in politics by opening an office in Brussels. Contributing to the development, funding and positioning of oncology at the European level is one of ESMO's ambitions. Taking care of the future of ESMO members and patients implies that the Society takes action to raise political awareness on issues that affect the constantly evolving environment of oncology.

ESMO addresses global inequalities in cancer care through statistical analysis of data concerning the discrepancies in the prerequisites for the practice of oncology in Europe and developing countries. The summary reports from this data analysis will help identify necessary improvements in the infrastructure of those countries that have less than optimal healthcare system. They will indicate how to face the challenge of reducing disparities in the quality of care available to patients residing in different European countries. They will also provide further evidence of the need to recognize medical oncology as an independent specialty throughout Europe and globally.

Standardized training in medical oncology, based on a solid background in internal medicine, has been defined in the *Recommendations for a Global Core Curriculum in Medical Oncology*, produced by ESMO in joint collaboration with the American Society of Clinical Oncology (ASCO). Another ESMO-ASCO joint publication is the Consensus Statement on Quality Cancer Care, published in 2006, which outlines the basic needs and rights

of cancer patients to the highest level of care.

Information, knowledge, and experience combine to form the backbone of excellence in clinical practice. To this end ESMO is a platform, offering a wide range of educational and scientific tools, such as:

- ESMO Congresses focus on both state-of-the-art educational sessions and the most recent developments in oncology research and technology.
- ESMO Conference Lugano (ECLU) provides a comprehensive overview of state-of-the-art oncology for major cancer types and special interactive sessions that focus on the needs of young oncologists, including an Academy of Oncology.
- ESMO International Symposia (EIS) concentrate on multidisciplinary approaches to specific fields of oncology.
- ESMO Partnership Meetings allow the Society to collaborate with other prominent oncology organizations in meetings on topics such as translational research, targeted therapies, prevention and organ-based tumors.
- The ESMO Examination in medical oncology certifies medical oncologists and is required to practice medical oncology or be a Full member of medical oncology societies in several European countries.
- ESMO accredits and supports educational courses, virtual meetings and Internet-based projects, thereby expanding the ESMO global network.
- ESMO, together with the Organization of European Cancer Institutes (OECI), seeks to identify the necessary criteria for medical oncology departments in comprehensive cancer centers.
- Following the publication of the *ESMO Policy on Palliative and Supportive Care*, the Society now accredits 'Designated Centers of Integrated Oncology and Palliative Care' that meet a comprehensive list of criteria and are capable of providing specific training in this important aspect of patient care.
- *ESMO Clinical Recommendations* assess diagnosis and treatment of various cancers. They are intended as guidelines for clinical practice and prerequisites for basic healthcare services.
- For ESMO members who seek a specialist's opinion on difficult and complicated cases, a Web-based Clinical Discussion Forum that allows them to consult directly with ESMO Faculty members is available on the ESMO Web site.
- For young oncologists, ESMO offers a career development program of fellowships, translational research unit visits, masterclasses, special educational activities, oncology handbooks - and much more.
- ESMO awards an ever increasing number of grants and fellowships with the aim of providing scholarships to exceptional, young oncologists.

The ESMO Foundation, since 2004, has been supporting ESMO's educational activities, ranging from specific training of young talented people to educational programs of the highest quality in cancer care and prevention, as well as activities in translational and clinical research.

The great strides and improvements that are on the horizon bring with them the need to transform a wholly scientifically-oriented organization into a Society that is willing and able to face the multifaceted aspects of cancer care and research. As the voice and driving force of medical oncology in Europe, ESMO is eager to continue to expand its role in multidisciplinary oncology, in order to meet the challenges that lie ahead.

More information on ESMO and its activities is available at **www.esmo.org**

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