



European Society  
for Medical Oncology

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## **Commission public consultation: Assessment of the community system of Pharmacovigilance**

- **response from the European Society for Medical Oncology (ESMO),**

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### **1. Type of stakeholder: European Society for Medical Oncology (ESMO)**

ESMO is the only European professional society providing education and clinical guidelines for medical oncologists. 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, hospital pharmacists, and oncology nursing. With a worldwide membership base, of 4,500 members, ESMO is represented in every European country and the major geographical areas of the world.

Since its inception in 1975, ESMO has consistently promoted its belief that every cancer patient is entitled to the best possible treatment available. The use of medicine is now a fundamental aspect of cancer therapy and, consequently, cancer patients need to be treated by qualified medical oncologists. ESMO supports multidisciplinary oncology and through its flagship scientific journal, *Annals of Oncology*, publishes research results on all aspects of clinical oncology.

ESMO communicates regularly with its members through its Newsletters, E-News, Presidential emails and the ESMO Web site. Major ESMO activities include:

- Publishing in November 2004, *Recommendations for a Global Core Curriculum in Medical Oncology*, in joint collaboration with the American Society of Clinical Oncology (ASCO).
- 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 Congresses** (annual as of 2009) focus on both state-of-the-art educational sessions and the most recent developments in oncology research and technology.
- **ESMO Conference Lugano (ECLU)** provides an annual 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 (prostate cancer, gastrointestinal cancer and GIST, supportive care, chest tumors, and several others under development).

- **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.
- **ESMO accredits and supports educational courses**, virtual meetings and Internet-based projects, thereby expanding the ESMO global network.
- Following the publication of the *ESMO Policy on Palliative and Supportive Care*, the Society has moved ahead to identify '**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. The list of centers recognized by ESMO is available at [www.esmo.org](http://www.esmo.org).
- **ESMO Special Programs** are tailor-made programs for colleagues in Central and Eastern Europe as well as those in less developed regions.
- **ESMO Minimum Clinical Recommendations** assess diagnosis and treatment of various cancers. They are intended as guidelines for clinical practice and prerequisites for basic healthcare services. The guidelines are freely accessible at [www.esmo.org](http://www.esmo.org).
- 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 will award almost 40 **grants** in 2006, with the aim of providing scholarships to exceptional, young oncologists. Grants will be awarded in the following categories:
  - ESMO Fellowships
  - ESMO Translation Research Unit grants
  - ESMO Palliative Care research grants
  - ESMO Developing Countries research grants
  - ESMO Foundation grants

Donations to the **ESMO Foundation** help support ESMO activities as well as cancer research.

More information on the Society and its activities can be found at [www.esmo.org](http://www.esmo.org)

## 2. Comments:

- Pharmacovigilance is a very important system to detect early and late sequelae from medical treatment. This is particularly important for drugs which should not induce severe toxicity, at least not in the long-term, and in particular also for new registered drugs.

In oncology, chemotherapeutic drugs, including supportive drugs, have by nature some major toxicities as known side-effects which are not relevant for the Pharmacovigilance system. However, sometimes specific side-effects appear only after a longer time of use and - since they are rare - will only be detected after frequent use of this drug in the oncology community.

Furthermore, late sequelae from chemotherapy, radiotherapy and in particular from the new targeted drugs might appear after many years and could be detected by the Medical Oncologists in the framework of follow-up investigations. In particular the new targeted drugs with antivascular/antiangiogenic effects might result in late toxicities and sequelae which are not known today; these drugs are used often for a prolonged time and might cause damage to a vascular tissue in important organs after

a longer period of use. The current experience is only limited from 1 to a maximal of 2 years of application. Therefore, the members of the oncology societies in Europe are an excellent source for registration of such unexpected acute or late toxicities.

- For this matter the community system in the different countries, as described in the Fraunhofer Institut Report, can be used by the Medical Oncologists in their own countries; however, in addition the central organization ESMO, through its strong European network, can be helpful to collect this information and disseminate it to the central Pharmacovigilance system. Such a mechanism could strengthen the community Pharmacovigilance system and the Pharmacovigilance system overall.
- Furthermore, information about the Pharmacovigilance system and results coming out from this system can be disseminated to ESMO members to make them aware of current issues. In addition, ESMO members could be invited to share this information with other members of the Medical Oncology Community (Hospitals, Practices etc.) both on a national and an international basis. Therefore, ESMO could help to increase the efficacy of the dissemination of Pharmacovigilance information.
- A further possible option for collaboration with ESMO members could be the possibility for ESMO members to be consulted by officers of the Pharmacovigilance system in case of upcoming questions resulting from the findings of the community Pharmacovigilance system. ESMO has a Faculty List and many members who are experts in specific fields of Medical Oncology and also associated fields. They could provide expert opinion and support in decision-making or for further investigations. This is an offer from ESMO which could further increase the strength of the Pharmacovigilance system if adequately used. In particular, ESMO could provide the contact details of the Medical Oncologists in the specific region where reports arise and ask these ESMO members, if there are questions related to the field of Medical Oncology, to disseminate specific information to Medical Oncologists.

### **3. Conclusion:**

In summary ESMO, as well as ESMO members, could be a meaningful and helpful part of the overall Pharmacovigilance system. The system in general is very good. It would be very important to continually communicate concise information about the Pharmacovigilance system to ESMO members and to raise their awareness about the reporting of late side-effects. ESMO remains open to discussion as to how this topic can be included within the program of its educational activities.



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