



**EUROPEAN CANCER PATIENT COALITION'S RESPONSE TO:
EMEA/CPMP Working Group with Patients Organisations –
Outcome of Discussions:
Recommendations and Proposals for Action
Executive Summary**

Introduction

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

- Nothing About Us, Without Us!
- Promoting the fundamental rights of European cancer patients
- Increasing cancer patients' influence over European health policy
- Ensuring timely access to appropriate prevention advice, treatment and care
- Promoting the advancement of cancer research

Currently, ECPC has 87 full members and 12 associate members from 8 EU Member States and represents patients with cancers of the commonest sites such as lung and colorectal cancer to the rarer cancers such as multiple myeloma and chronic myeloid leukaemia. At present, the Coalition is governed by a steering committee consisting of:

- Lynn Faulds Wood (UK), Lynn's Bowel Cancer Campaign
- Heide Preuss (Germany), Mamazone
- Ekke Buechler (Austria), Selbsthilfe Prostatakrebs
- Jan Geissler (Germany), Leukaemia Online
- Tom Hudson (Ireland), Europa Uomo – the European Prostate Cancer Coalition
- Claudia di Loreto (Italy), Assoc Italia Malati di Cancro (AIMaC)
- Patricia Huijbreghts (the Netherlands), the Dutch Federation of Cancer Patients' Organisation (NFK)
- Jesme Baird (UK), the Roy Castle Lung Cancer Foundation
- Kathy Redmond (Italy), the European School of Oncology

Four of these committee members are cancer survivors; the others represent cancer patient organisations and the organisation that is the Coalition's main source of

funding – the European School of Oncology (Kathy Redmond). Further information about ECPC is available from www.ecpc-online.org

In June 2004 the Coalition held its first Masterclass in Cancer Patient Advocacy that was attended by over 100 cancer patient representatives from thirty three countries world-wide (including most of the EU Member States). An entire session of the Masterclass was dedicated to issues surrounding cancer drug approval and access. Speakers included Isobelle Moulon (EMA), François Houyez (EURORDIS), Heide Preuss (Mamazone) and Sandy Craine/Elizabeth Rees (CML-Support.org). Delegates were provided with copies of the Executive Summary of the *EMA/CPMP Working Group with Patients Organisations – Outcome of Discussions: Recommendations and Proposals for Action* and invited to provide the Coalition with feedback on the proposals. What follows is a compilation of feedback received to date.

Background

Cancer is an important public health problem. Every minute approximately 4 European Union citizens are diagnosed with the disease and at least 2 die from it. Despite the huge amounts of money that have been invested in the war against cancer, outcomes remain poor for many of the 200 different cancer types. Most cancers are treated by a combination of surgery, chemotherapy and radiotherapy. Cytotoxic chemotherapy is associated with a number of burdensome and sometimes life-threatening side effects (eg. nausea, vomiting, neutropenia etc.). Many side effects occur when patients are at home and therefore patients play a pivotal role in detecting and reporting side effects early and in managing their consequences. Chemotherapy is mostly administered in an in-patient or ambulatory care setting. The drugs are normally reconstituted centrally in a pharmacy and administered by experienced doctors and nurses (for health and safety reasons). Therefore, cancer patients rarely, if ever, see the package leaflet that accompanies their drugs. This fact, coupled with the fact that the quality of and access to patient information about cancer medicines varies between and within EU Member States, means that the informational needs of many European cancer patients are not met.

The informational needs of “internet savvy” patients are met to a much greater degree than e-excluded patients. Unfortunately, the vast majority of European cancer patients fall into the latter group. This is evidenced by the fact that Internet usage is low in many Southern European countries and is particularly low in the new EU Member States. The Internet tends to be used by English speaking, young men who live in metropolitan areas. Since cancer is a disease of old age and most Europeans do not speak English, either as a native or a second tongue, it is not surprising the majority of cancer patients fall into the digitally excluded group. Nor is it particularly surprising that last year a Eurobarometer survey showed that only a quarter of European citizens use the Internet to access information about health. This points to the importance of providing information from a number of different sources.

Discussions about the regulation of cancer drugs in Europe are important for cancer patients, particularly since next year, once the new pharmaceutical legislation comes

into force all cancer drugs will be approved via the centralised procedure. Moreover, nearly half of all products designated as orphan medicinal products by the European Commission are indicated for rare cancers. EMEA has an important role to play in ensuring European cancer patients get timely access to innovative cancer drugs and information about how to take these drugs in a safe and proper manner. ECPC welcomes the opportunity to comment on this proposal and provide some suggestions for other important actions from the perspective of the European cancer patient community. We have highlighted what we consider to be the most important actions in appendix 1.

Feedback on Recommendations and Proposals for Action

Transparency and dissemination of information

ECPC endorses and supports the recommendations and proposals for actions made by this subgroup however would like to make the following additional proposals:

- Pilot testing should also be done on translated patient information materials to ensure that the readability level does not change as a result of translation
- A best practice example of how to develop a disease specific area on the EMEA Web-site can be found at the Oncology Tools section on the US Food and Drug Administration (FDA) site (<http://www.fda.gov/cder/cancer/index.htm>)
- FDA press releases and Talk Papers also provide good models for developing patient-friendly press releases about important drug approvals or safety messages
- It is vital that mechanisms for informing patients about cancer medicines other than the EMEA Web-site and product information/package leaflets (PL) are put in place (for the reasons outlined above). Printed materials need to be made available and a realistic dissemination strategy developed with input from all stakeholder groups (i.e. EMEA, NCAs, doctors, nurses, pharmacists and patient organisations).
- FDA sends regular e-mails to members of medical and nursing organisations to communicate important information about new drug approvals and providing safety updates. EMEA could base its efforts to reach out to professional organisations on the FDA model.
- Special efforts are required to ensure that hospitalised patients receive the PLs that accompany their drugs
- Patient and professional organisations should be encouraged to make links from their Web-sites to the EMEA Web-site
- Where possible the process and outcomes of CPMP's decision making process should be made public so that patients can understand why medicines are, or are not, being made available to them
- The timing of information is important – it would be useful to know when an application for marketing authorisation has been submitted and at what stage of the CPMP review process the application is at.

Product information

ECPC endorses and supports the recommendations and proposals for actions made by this subgroup however would like to make the following additional proposals:

- EURORDIS does a tremendous job in representing the needs of patients with rare diseases, however, does not concentrate its efforts on the specific needs of cancer patients with rare diseases. For orphan drugs, it is probably more helpful for patients to be directed to a high quality site that contains information about the disease in question.
- More effort is required to define what type of information needs to be included in PLs to ensure that patients can take their medicines in a safe and proper manner and detect and act on side effects as early as possible (ie. To determine patients' informational needs about medicines)
- Many cancer patients take herbal medicines and alternatives therapies whilst undergoing treatment for cancer. The potential interaction of cancer medicines with these therapies should be addressed in PLs.

Pharmacovigilance

ECPC endorses and supports the recommendations and proposals for actions made by this subgroup – the Coalition has no further suggestions to offer in this area.

Interaction between EMEA/CPMP and Patient Organisations

ECPC endorses and supports the recommendations and proposals for actions made by the Working Group however would like to make the following additional proposals:

- Since patients are the people who will actually benefit or be denied access to an innovative cancer drug there should be much greater patient involvement in decisions about whether or not specific drugs are approved.
- ECPC would like to see greater consultation with patients about the designation of promising agents for fast track evaluation. Patients can help CPMP to understand more clearly the impact of the disease on patients and the difficulties they face. They can also comment on where the drug under consideration actually fits into the management of the disease.
- There should be cancer patient representation on the Oncology Therapeutic Advisory Group
- In order for patients to contribute effectively to discussions about drug regulation they need to develop an understanding of the processes and procedures involved. FDA has played a leadership role in equipping patients with the knowledge and skills they require to contribute to the drug approval process through the establishment of its Cancer Liaison Program (<http://www.fda.gov/oashi/cancer/cancer.html>). Relevant aspects of this programme are explained in Appendix 2. EMEA could develop a similar programme to make sure that all patient representatives that serve on

CPMP/EMEA committees, or contribute in some way to the regulation of drugs in Europe, possess the skills necessary to undertake these roles.

Conclusion

ECPC very much welcomes the steps EMEA is taking to involve patients in the regulation of drugs in Europe and ensuring that patients get timely access to novel agents. The Coalition would like to congratulate the EMEA/CPMP Working Group and acknowledge its Trojan efforts in preparing these important proposals for changing the status quo. The proposals represent an important way forward for improving information provision and securing increased patients involvement in various aspects of EMEA's work. ECPC looks forward to collaborating with EMEA in the future and hopes that a representative of the Coalition is invited to attend the 2nd EMEA/CPMP Workshop for Patient Organisations that is due to be held in Autumn 2004.

APPENDIX 1: Most important actions identified by the European cancer patient community

Transparency and dissemination of information

- Availability of all information for patients in all official EU languages.
- Further development of the EMEA Website with inclusion of information on organisations where patients can find additional relevant information. In the meantime, a lot of patients use the internet to receive medicinal information.
- Introduction of multi-lingual navigation of the Website.
- Additionally to the EPAR a patient-friendly version.
- “Questions and Answers” documents on case-by-case to address specific situations affecting the use of medicines.
- Also interesting is the timing of information before CHMP opinion (e.g., submission of applications, procedural time table for specific products).
- EMEA should improve collecting, communicating and providing information to patients.
- Better communication between EMEA, representatives of regulatory bodies, health education officers, patients groups and consumers organisations.
- Information on all medicines approved in the EU should be made available to patients organisations.
- Information about the availability of medicines across the Member States.

Product information

- Involvement of Patients Organisations at an early stage when drafting a package leaflet, participation of patients in the Day-150 meeting.
- Inclusion of a reference to the EMEA Website where patients can find the latest information available on the product and a statement at the end of PL where the latest approved information is available.
- Possibility for patients to send comments to the EMEA on readability/quality of PLs.
- Patients associations should receive important new or updated draft guidelines for comments.
- Increase of readability of PLs to be understandable to most patients.
- Review of the Guideline on Readability (1998) with active involvement of patients associations at an early stage.

Pharmacovigilance

- Improved reporting on pharmacovigilance data
- Possibility to patients organisations to send summarised reports to the NCAs.

Interaction between EMEA/CPMP and Patient Organisations

- Effort to define criteria for patient organisations
- Pro-active consultation of disease specific groups
- Opportunity for patient organisations to participate in CPMP Working Groups (eg. TAGs)
- Interaction with patients as experts on their disease

APPENDIX 2: FDA's Cancer Liaison Program

Cancer Drug Development Patient Consultant Program

This programme helps to incorporate the perspective of patient advocates into the drug development process by providing cancer patient advocates with the opportunity to participate in the FDA drug review regulatory process. To accomplish this, the FDA selects and trains cancer patient advocates for the Program. The selected cancer patient advocates serve as patient consultants in the pre-approval, clinical trial phase of cancer drug development. The patient consultant provides advice to the FDA and to the drug sponsor on topics such as clinical trial design, endpoint determination, expanded access protocol development, and clinical trial patient recruitment strategies. Cancer patient advocates are chosen by the Office of Special Health Issues (OSHI) in collaboration with the Division of Oncology Drug Products (DODP), and the Advisors and Consultants Staff in the Center for Drug Evaluation and Research. Patient consultants are hired as Special Government Employees and, therefore, subject to FDA's conflict of interest and confidentiality regulations that govern each FDA employee, consultant, and advisor. The cancer patient advocates chosen to serve, as patient consultants are selected to participate in meetings by matching a specific cancer and the proposed indication for the new cancer drug being developed. The patient consultant participates in meetings (via telephone¹) between the FDA and drug companies. The patient consultant receives approximately two days training from FDA staff (at FDA's Rockville location²) in preparation for these meetings.

Cancer Patient Representative Program

As part of the "FDA Initiative on Reinventing the Regulation of Cancer Drugs," the Cancer Liaison Program is a process for recruiting, assessing, and selecting patient representatives to serve as members of cancer-related advisory committees in the Center for Drug Evaluation and Research (CDER), the Center for Biologics Evaluation and Research (CBER), and the Center for Devices and Radiological Health (CDRH). This initiative provides representation for cancer patients and ensures that the selection process provides for broad representation in the nominee pool.