Template for responses (DEADLINE 12 May 2006 responses should be e-mailed to peter.arlett@cec.eu.int)

RESPONSE TO: Commission Public Consultation: As Assessment of the Community System of Pharmacovigilance

Your response will be put on the Commission's website.

Name[1]: *European Cancer Patient Coalition, Hildrun Sundseth, Head of EU Policy*

Type of stakeholder (e.g. patient/ healthcare professional/ regulator/ industry):
patient organisation, over half of our Board members are cancer patients, survivors or carers

Organisation (e.g. European patient group or National industry association - if relevant):
European umbrella organisation of over 180 cancer patient groups representing the big cancers to the rarer cancers.

Your comments:

- **on the specific areas highlighted in the Commission sponsored study which can be summarised as follows:**

We fully agree with the Study's core recommendations to make the European System of Pharmcovigiliance more robust.

1. **Data sources and safety issue detection**
2. **The legal framework and new legal tools**
3. **Decision making in pharmacovigilance**
4. **Impact of communications and actions**
5. **Facilitation and monitoring of compliance with pharmacovigilance requirements**
6. **The need for quality management and continuous quality improvement.**

- **on your experiences of the Community system overall**

ECPC is just over two years old and our experience across Europe is this field is therefore somewhat limited. The system has been dispersed depending on the patient's country of residence and treatment. The Pharmacovigilance systems in cancer field have been somehow patchy and seemingly uncoordinated with long decision lines. We very much hope that with the new pharmaceutical legislation in place, medicines for cancer patients will now have to be centrally approved, which we are sure will provide the basis for a much more robust European Pharmacovigilance system to be implemented and constantly improved. Patients must be included in this process at all relevant stages.

- **on any part of the Community system (section 1 of this consultation paper describes the system and those involved directly)**

- **on how you could better contribute to the Community Pharmacovigilance system**

[1] requests for attendance at the workshops should be sent separately to peter.arlett@cec.eu.int and should include the organisation you represent and your contact details. The deadline for these requests is 31 March 2006.

Pharmacovigilance is an important public health issue which impacts greatly on patient safety. Patient groups have a vital role to play, but so far there is a lack of awareness among the general public and even patient groups how the systems functions, how they could interact with it and how to contribute.
We recommend that training tools for patients be developed that empower patients better to understand and interact in this field, and also enable them to inform and educate their members. Patient groups often do not have the necessary expertise and funds for such initiatives. In our view it would be most helpful and contribute to patient and medicines safety overall for such training programmes to be funded by an independent source, such as the Community Public Health Programme.

- **on suggestions to strengthen the Community pharmacovigilance system.**

We fully support that for centrally authorised products, EMEA requests that the company/marketing authorisation holder is responsible for collecting pharmcovigilance data from specific target groups.

In view of the expected adoption of the Paediatric Regulation, we recommend that the Community system take a very proactive approach in the field of paediatric pharmacovigilance by developing specific guidelines in this sensitive area and establishing an inventory of all sources of data collection at EU level. Side effects will probably be different from adults and may have yet unforeseen long-term consequences, which require better comparison and long-term data collection.

- **any other comments**

Any effective Pharmacovigilance system depends on the capacity to communicate safety information effectively, without delay and without undue alarm to healthcare professionals and patients. One immediate and helpful action for patient safety and Pharmacovigiliance would be that patients when they are hospitalised and receive medicines also receive the Package leaflet. All too often the patient and/or his relatives/carers are considered passive actors. Patients are given medicines without having read and fully understood the PL.