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]: Maria Judith Márquez Pradera

Type of stakeholder (e.g. patient/ healthcare professional/ regulator/ industry): healthcare professional and medical adviser for the pharmaceutical industry

Organisation (e.g. European patient group or National industry association - if relevant):

Your comments:

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

  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**

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

DATA COLLECTION:

Registries

- **MAH are asked to create health/ drug registries in order to monitor eventual adverse effects related to a medicinal product but there is no guidance on how to establish these registries in some of the member states. It would be useful to elaborate general recommendations regarding this issue.**
- **There are different parties that should collaborate in the creation of these registries: regulatory authorities, MAH, associations of patients, medical societies/ associations, etc.**
- **The cost of creating a registry should be taken into account (a National/ European health policy for promotion and support of registries should be considered).**

[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.

- **Access to public or private health/ drug registries should be easier for the interested parties, including MAH. The name of public or private health/ drug registries and relevant information about them (e.g., objectives, functions and contact details) should be made available for all the interested parties.**

Healthcare professionals

- **Implementation of incentive measures in order to motivate notification of adverse drug reactions by healthcare professionals should be taken into account. Examples of measures not related to economical compensations are: 1) for the continuing evaluation of healthcare professionals, notifications of adverse drug reactions by the healthcare professional per year should be considered a value or a credit point and should be taken into account. 2) For job applications, notifications of adverse reactions by the healthcare professionals and included in his/ her *curriculum vitae* should be considered a value and should be taken into account.**
- **Healthcare professionals should receive more information, training and guidance on reporting adverse drug reactions. Guidance about this item should be harmonized in the EC.**

Literature Reports

Publication of adverse drug reactions (case reports) in the scientific literature should have a legal frame. Previous notification of the adverse drug reactions to the concerned competent authority or the MAH, inclusion of the commercial name of the suspected drug as well as the active principle in the literature report should be mandatory.

OTHER ACTIONS

Post-authorisation Observational Studies and Pharmacoepidemiological Studies

- **Legislation on Post-authorisation Observational Studies and Pharmacoepidemiological Studies is lacking in some member states and the EC. General guidance and recommendations are also lacking.**
- **Many post-authorisation studies sponsored by the pharmaceutical industry are of poor quality.**
- **These studies should be regulated appropriately and legislation should be harmonized in the EC.**

Education on Pharmacovigilance in the pharmaceutical industry

- **Education on Pharmacovigilance for other collaborators (all?) not only to the pharmaceutical sales representatives in the pharmaceutical industry should be mandatory and should be harmonized in the European Union.**
- **Guidance for industry on education on pharmacovigilance for its staff is necessary. Some items (e.g., need for continuing training on Pharmacovigilance, contents of the educational activity) should be taken into account and should be harmonized in the European Union.**

Education on Pharmacovigilance for healthcare professionals

Training activities on Pharmacovigilance for healthcare professionals should be promoted by the pharmaceutical industry, the regulatory authorities and other entities (e.g., medical societies, association of patients) and could be mandatory in hospitals and primary care centres.
Collaboration among the different parties should be mandatory (regulatory authorities, MAH, other institutions) in this regard.

Education on Pharmacovigilance for consumers

Educational activities for consumers should be considered by regulatory authorities, MAH, other institutions and collaboration of the different parties should be mandatory.

COMPLIANCE WITH PHARMACOVIGILANCE REQUIREMENTS

- **Audits (internal or external) and inspections of pharmaceuticals companies should be done more frequently.**
- **Results of audits, audit reports and subsequent corrective actions should be sent to the competent authority(ies) by the MAH.**

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

See the comments made above.

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

See the comments written above.

- **any other comments**