Commission Public Consultation:
Assessment of the Community System of Pharmacovigilance

Name: European AIDS Treatment Group
Type of stakeholder: patient
Organisation: European patient group

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

- Need to harmonize the different sources of safety information between member states (Individual Case Safety Reports, PSURs, registries, consumption data, safety studies).
- Develop & implement common set of statistical tools to be used by member states.
- Optimize national data bases.
- Make sure that Marketing Authorization Holders fulfill their role of first-line signal detection for both centrally and nationally authorized products.
- Make sure that safety reporting is easy, accessible to all stakeholders, not cumbersome or time consuming (public electronic terminals? – internet?).
- Facilitate involvement of healthcare professionals (doctors, nurses, pharmacists) and patients.
- Clarify type of safety issues to be reported (need to include known side effects?).
- Distinguish between safety & pharmacovigilance questions.

2. The legal framework and new legal tools

- Prioritize mandatory phase IV studies for innovative medicines.
- Implement no blame system on AE reporting.
- Regulate internet pharmacies.
- Harmonize legal framework and its implementation between Member States.

3. Decision making in pharmacovigilance

- Involve patient representatives in PSUR/CHMP decisions.
- Involve patients/representatives in reevaluation of risk/benefit ratio in approved medicines.
- Make adequate use of external expertise.

- Harmonize & streamline process within Community.
- Identify and remove disparities between Member States.
- Improve coordination with international partners.

4. Impact of communications and actions

- Harmonize & streamline mechanisms to inform doctors, pharmacists, patients and the general public in Member States.
- Improve impact on prescription behaviour.
- Consult patients/patient groups in decision making prior to communications and actions.
- Assess outcomes of regulatory actions.

5. Facilitation and monitoring of compliance with pharmacovigilance requirements

- Collaboration between Member States should be improved by implementation of multinational phase IV cohort studies (large number of patients needed to capture rare AE).
- Measure industry compliance.
- Establishment of confidentiality between patient organisations and pharmaceuticals to balance the need for timely information and commercial and legal concerns when sharing such information in advance of public announcements.

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)
• on how you could better contribute to the Community pharmacovigilance system
• on suggestions to strengthen the Community pharmacovigilance system.
• any other comments

- Patients (especially those with chronic conditions) understand that effective medicines come with side effects.
- Assess different approaches of centralization vs. harmonization carefully – need to find appropriate balance.
- Need to prioritize: focus on pragmatic steps and innovative, centrally approved medicines first.
- Invest in capacity building of patients/patient groups.
- Look at medicines used outside of prescription area.
- Consider increasing use of OTC drugs.
- Harmonize electronic patient records between Member States and ensure protection of individual data.

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