

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

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My comments :

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

In respect to : Data source and the safety issue detection

At the Annex1 : I agree that the data on the use of medicines are very helpful in evaluating the incidence of side effects and making a comparisons between countries (data on use are the denominator of the equation in calculating the risk ratio) . The medicines utilisation studies in my point of view are the better way to ovoid a labouring in the dark. Unfortunately, pharmaceutical industries which use the data to identify fields of opportunity for research and development, and to monitor his own progress in a competitive market, are not fully collaborating with pharmacovigilance. It is a legal tool for the future.

- **On my experience of the Community system overall**

There is a need to separate the marketing authorisation and pharmacovigilance in terms of fundraising, in order to ovoid conflicts of interests and pushing up the pharmacovigilance to better protection of public health by giving her an financial autonomy (governmental fundraising only) moral and scientific authority to the institution of pharmacovigilance. This is the case in my country which pharmacovigilance is independent from the marketing authorisation given by the director of pharmacy of the ministry of health (administrative authority).

- **On how I could contribute to the Community pharmacovigilance system**

At the Annex3 : Initiative that are included in the European risk management : We think that the area which require research with respect to the development of novel method, is the transfer of the very huge knowledge available now in medicine to skills to equip the physicians, pharmacists and nurses to prescribe, to dispense and to take a better care by developing attitudes compatibles with humanitarian recommendations, cognitive learning and psychomotor skill of good practice. Briefly, all what is not given at undergraduate teaching in the faculties. In Algeria, we teach teachers of pharmacotherapy and pharmacy to ovoid ineffective, unnecessary and expensive or unsafe medicines by using logical step-by-step method in pharmacotherapy (Groningen method), and skill-based method in pharmacy (Algiers method). Development of problem-based and skill-based teaching in medicine and pharmacy is the corner stone, in our opinion, for promoting rational use of medicines and to prevent inadequate therapy.

Algiers 30 March 2006

