Dear Dr. Arlett,
The EU PhRMA PV Working Group has been developing an outline for Good Pharmacovigilance Practices (GPVP). During a one day workshop the team members discussed scope, objectives and main topics to be covered under GPVP. It was the intention of the group to provide input into an international, preferably global initiative. When we became aware that neither ICH nor CIOMS pursued this topic, the team compared the final FDA guidance document on 'Good PV Practices and Pharmacoepidemiologic Assessment' with our GPVP topics. This comparison revealed important gaps and thereby confirmed the need for a European or global initiative on GPVP. Almost 20 years after the implementation of Good Clinical Practices the time seem to have come to develop similar standards for Pharmacovigilance.

The EUPhRMA PV team recently had the opportunity to discuss this matter with Dr. June Raine. She encouraged us to provide our input to you within the EU Commission consultation process. Dr. Raine indicated that the deadline for comments will be May 31, 2006.

Please find attached the table of contents for a GPVP concept paper. Such an initiative would require the collaboration of the different stakeholders involved in pharmacovigilance. Our group acknowledges the fact that such a concept paper will require substantial resources. We envisage that timely efforts would require a split of topics among various task forces. Experts from our group would be willing to contribute to corresponding task forces or working parties.

Please let us whether or not you wish to further discuss our ideas with respect to Good Pharmacovigilance Practices.

Looking forward to your response,
Your sincerely, <<20060526_Good PV Practice Document-TOC .doc>>

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Good Pharmacovigilance Practice Document

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