**Assessment of the functioning of the "Clinical Trials Directive" 2001/20/EC**
**Public Consultation Paper**

**Comments from EBE**

The European Biopharmaceutical Enterprises (EBE) would like to acknowledge the opportunity to participate in the public consultation for the *Assessment of the functioning of the Clinical Trials Directive.*

The EBE is a Trade Association representing European based biopharmaceutical manufacturers. Our current membership is some 65 companies, of which about two thirds are SMEs.

Our sister organization, EFPIA, will submit detailed input covering the boxed "consultation items" identified in the Consultation Paper and the EBE would like to fully endorse these comments.

In addition, the EBE would like to draw attention to the specific challenges faced by SME companies when developing new products for rare disorders that affect a limited number of patients. Clinical trials for such products will usually need to be conducted in several countries in order to enroll adequate patient numbers. The management of these trials poses particular problems for SMEs:

**Administrative and cost burdens**

- Divergent requests from Member States for changes to protocols, delays the initiation of multinational rare disease trials and complicates their management.
- Regulatory processes and administrative requirements vary significantly between the different European Member States.
- Information about additional national requirements and processes is not readily accessible.
- Typically, SMEs do not have in-house resources to track and manage national regulatory documentation, translations and approval processes.
- The necessity to turn to consultants and contract research organisations for help to solve the issues above drive up the costs for SMEs that, in most cases, have only small or no sales revenues.

In conclusion, we would like to emphasise that the current requirements of the Clinical Trials Directive impose very real challenges for the resources of an SME. It is recognized that the overall goal must be to safeguard patient health but the administrative and cost burden should not act as an impediment to the development of new and innovative medicines by SMEs.

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