EUROPEAN PARKINSON'S DISEASE ASSOCIATION

1 Northumberland Avenue
Trafalgar Square
London WC2N 5BW
United Kingdom
Tel.: +44 (0) 207 8725510
Fax: +44 (0) 207 8725611

6 May 2011

EPDA response to the review of the Clinical Trials Directive 2001/20/EC

The European Parkinson's Disease Association (EPDA) welcomes the opportunity to contribute to the European Commission's public consultation paper. EPDA is a not-for-profit organisation and is the only European umbrella organisation for Parkinson's disease. It represents 45 member organisations and is the advocate for the rights and needs of over 1.2 million people with Parkinson's and their families. EPDA fully supports and advocates for the rights of patients with serious diseases, such as Parkinson's disease, to participate in relevant and high quality clinical trials.

The EPDA supports the need to meaningfully address the patients' views in the review process to ensure a better, more patient-centred approach to the design and regulation of clinical trials. The EPDA strongly believes that patients' participation in clinical trials should be encouraged and all should be done to increase participation rates which are currently declining. We would suggest the European Commission considers conducting a campaign to increase public awareness of the benefits to the individual and to society.

The EPDA believe that patients' representation in Ethics Committees is of paramount importance and this issue should be addressed through legislation by including specific provisions in the Clinical Trials Directive and, that the Directive should include provision for *voluntary* patient involvement in ethics committees. Patient involvement can offer significant benefits and ensure that the patient perspective is genuinely recognised. Patient organisations can also play an important role by providing information for patient communities they know well, they can help engender trust and increased participation in clinical trials.

We believe the European Commission is fully aware of the need to lessen the administrative burden whilst still maintaining participant's safety. This is particularly relevant for chronic degenerative conditions where time is of the essence for access to new medications that might have a significant impact on disease progression. People who have a chronic neurodegenerative disease, such as Parkinson's Disease, may also have a different perception of risk linked to a clinical trial for innovative treatment. They may analyse the risks & benefits differently and be more willing to take higher risks for a lesser guarantee of benefit.

The EPDA emphasise that patients' access to quality information *before* and *after* clinical trials is essential. Meaningful informed consent should be regarded as a pre-condition for the start of any clinical trial. The Directive should include a provision that the Commission will prepare guidelines in consultation with patient organisations on the information that should be included, its user-friendliness, and the process of obtaining informed consent.

The EPDA calls for transparency concerning the results of clinical trials and for patients' to have access to treatment following the clinical trial completion. Patients often have little access to the results of the clinical trial, this decreases the willingness of patients to participate in a follow up or second clinical trial. In addition it should be the responsibility of researchers and sponsors to secure affordable, post-trial treatment to all trial participants.

In conclusion, the EPDA welcomes the revision of the Clinical Trials Directive to ensure that patients get an opportunity for meaningful contribution to the entire clinical trials process. Clinical trials influence access to new and improved medicines and are a major mechanism for responding to unmet medical needs. Clinical Trials represent an enormous investment for everyone involved, not least the patients, it is vital they continue to be conducted within Europe.