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Submission to the European Commission re Revision of the "Clinical Trials Directive" 2001/20/EC

Introduction

Parkinson's UK is delighted to be afforded the opportunity to submit evidence to the European Commission Revision of the "Clinical Trials Directive". Parkinson's UK represents 120,000 people in the UK with Parkinson's in addition to those affected by the condition including relatives and carers. Our goal is to improve treatments available for people with Parkinson's and to ultimately develop a cure for the condition. This will be achieved when people with the condition can live a life that is free from the symptoms. People with Parkinson's want to ensure that potential treatments are brought into the clinic with the minimum delay while still remaining with a controlled safety network. There is a unique opportunity for people affected by Parkinson's to play a pivotal role in shaping this process. However, a streamlining of the process of therapeutic development should not result in a compromise of safety.

Consultation items 1 & 2

A single submission and assessment is the most appropriate for clinical trials. In is important that clinical trials of new therapies progress with the minimum of delay. However, the current system requiring individual national submissions and assessments is not appropriate and slows down the development of new and more effective therapies. A single point of application – i.e. an individual country – where an assessment is carried out and recommendations made for EU-wide adoption is the most appropriate system. These can then be adheedto by other countries where the trial is to take place.

Consultation item 3

The development of a committee of Member States under the auspices of the European Medicines Agency (EMA) to assess each application would be unnecessarily bureaucratic and expensive, considering that it is unlikely that all countries are likely to participate in specific trials. This is supported by the evidence contained within table 2 in the Annex. The aim of the revised guidelines is to streamline the process of initiating clinical trials and a complex committee structure is inappropriate in order to achieve that aim.

Consultation items 4 & 5

A coordinated assessment procedure (CAP) is the most appropriate for achieving the aim of streamlining the process and is already in place for marketing authorisations. Item (a) should be included within the scope of CAP. However, individual national ethical and suitability assessments in all participating countries are essential to ensure local accountability. Patient groups will have a particularly important role in these aspects of trial assessment.

Consultation item 6
In a case of disagreement, the matter should be referred to the Commission or Agency for a decision. This will ensure a consistency in the assessment and decision making processes.

Consultation item 7
The CAP should be mandatory for all clinical trials. This is the most appropriate approach to ensure compatibility throughout the Member States. In order to streamline processes, a universal adoption of the CAP is essential. Although a trial may be initiated within a single country, there is a high level of possibility that it will develop to include other Member States. The initial authorisation under the existing Clinical Trials Directive for one country would then necessitate a subsequent CAP application. This is inefficient and will slow down the development of multi-centre trials.

Consultation item 8
A pre-assessment of trial procedures is appropriate only if specific unambiguous guidelines are in place and these have been agreed and will be adhered to by all Member States. This will ensure that a proportionate level of assessment is in place for specific procedures and will be in keeping with the aims of the CAP.

Consultation item 9
The implementation of the CAP will be an appropriate mechanism to harmonise procedures and will lead to a more proportionate assessment of trial classification and assessment requirements.

Consultation item 10
The guidelines should be implemented equally irrespective of the trial sponsor.

Consultation items 11 & 12
A harmonisation of the assessment and reporting of risk is appropriate within the CAP. This will ensure continuity between Member States and will be essential for the streamlining of multi-national later stage clinical trials.

Consultation item 13
This approach is appropriate. It will ensure that there is a proportionate approach adopted when defining “medicinal products” and complements section 1.3.4 on the pre-assessment of trials. It will ensure that trials can commence at the earliest possible stage rather than a single assessment process being carried out for different products which will have specific risk and safety implications.

Consultation item 14
The removal of insurance/indemnisation requirements for low risk procedures is appropriate. It should be in parallel with the classifications defined in sections 1.3.4 and 2.3 which propose a specific classification of products

according to safety and risk. This approach is supported from the data in section 7 of the annex.

Consultation item 15
The most appropriate approach is to adopt a single sponsor. This will decrease the level of bureaucracy that is associated with multiple points of contact within an individual application.

Consultation item 16
It is not always possible to obtain consent for the trial of therapies for acute conditions due to the nature of the conditions themselves. Therefore, retrospective permission by the person and/or relative is appropriate.

Consultation item 17
If the CAP is to be adopted with the associated definition of the levels of the therapeutic interventions, it is vital that the same level of rigour is adopted for all trials, whether they take place within the EU or have been initiated outside the EU. Trialists should be encouraged to adopt the EU protocols in all trials irrespective of the country in which they are initiated. This will ensure that the development of trials within Member States that have been initiated elsewhere will be seamless and have minimal bureaucratic barriers.

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