EUROPEAN AIDS TREATMENT GROUP

Response to:

Concept paper of 9 February 2011 submitted for public consultation by the European Commission on the

REVISION OF THE "CLINICAL TRIALS DIRECTIVE" 2001/20/EC

Submitted by the European AIDS Treatment Group (EATG)

Brussels, 13 May 2011

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- **Single submission with separate assessment (Consultation item no 1)**

  We agree that a single submission would greatly reduce the administrative of sponsors for submission of documentation to the Member States concerned.

- **Single submission with separate assessment (Consultation item no 2)**

  We agree that a separate assessment would insufficiently reduce administrative burden. We see no specific interest or benefit for study participants by keeping assessments separate.

- **Single submission with subsequent central assessment (Consultation item no 3)**

  We disagree with the appraisal as it stands. Different ethical, national and local perspectives would affect only a few and distinct areas of research, such as research in stem cells or pre-natal diagnostics. On the other hand, we agree that the involvement of all Member States is not needed, as most trials are rolled out in six Member States maximum.

  A subsequent central assessment procedure could be a long term goal for the next revision.

- **Single submission with subsequent coordinated assessment procedure (Consultation item no 4)**

  In our opinion, the catalogue is complete.

- **Single submission with subsequent coordinated assessment procedure (Consultation item no 5)**

  We recommend aspects under a) and b) to be included in the scope of the CAP. The rationale for including items under b) is that all Member States concerned are allowed to provide input. This ensures sufficient consideration for eventual national differences on ethical aspects.

  There is currently no minimum standard regarding the composition and training for ethics committees in Europe. Especially, the inclusion of patient representatives in ethics committees should be mandatory. We refer to the „Report on The Procedure for the Ethical Review of Protocols for Clinical Research Projects in Europe and Beyond“ published by the European Forum for Good Clinical Practice EFGCP.

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Therefore, including items under b) would increase the quality of the ethical assessment, harmonise ethical standards in Europe and be beneficial for the trial participants.

- **Disagreement with the assessment report (Consultation item no 6)**

  We suggest that disagreements under Member States about the assessment under CAP, aspects under a) and b) should be resolved by referral to the Commission or the Agency for a decision at EU level.

  We believe this would result in a more harmonised approach throughout Europe and better protect the interests of trial participants.

- **Mandatory / optional use (Consultation item no 7)**

  We recommend CAP to be mandatory for all multinational clinical trials. We see no benefit in a CAP procedure for single-country clinical trials.

- **Tacit approval and timelines (Consultation item no 8)**

  We welcome the introduction of a "type-A-trial" concept, i.e. a risk based approach, where the assessment procedure is essentially limited to issues of data reliability. This should however not have implications for non-interventional trials and should not lead to enlargement of the scope of the Clinical Trials Directive. A clear definition of a non-interventional trial not falling under the scope of the Directive and an interventional trial falling within the scope is required.

  Therefore, we consider a pre-assessment to be workable in practice.

- **Limiting the scope of the Clinical Trials Directive (Consultation item no 9)**

  We suggest to better explain the distinction between interventional and non-interventional trials. A clear distinction should be made between observational studies and trials that imply an element of intervention with a medicinal product or a diagnostic and monitoring procedure.

  If the involved methodologies require prospective data collection or an element of intervention within what can be considered as current clinical practice, the trial should be classified as non-interventional.

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- **Excluding clinical trials by academic-commercial sponsors from the scope of the Clinical Trials Directive (Consultation item no. 10)**

  We agree with the appraisal. Proportionate requirements should apply independently of the nature of the sponsor ("commercial" or "academic-non commercial").

- **Streamlining rules for conducting clinical trials (Consultation item no. 11)**

  From a patient's perspective, we agree with the appraisal proposing more precise and risk-adapted rules regarding the content of the application dossier and safety reporting requirements. Detailed provisions on these topics can be included in Annexes to the basic legal act.

- **Clarifying the definition of "investigational medicinal product" and establishing rules for "auxiliary medicinal products" (Consultation item no. 13)**

  We agree with the combined approach to simplify, clarify and streamline the rules for medicinal products used in the context of a clinical trial.

- **Insurance / indemnisation (Consultation item no. 14)**

  We recommend removing insurance / indemnisation requirements for low-risk trials only and optional indemnisation by Member State, taking into account the national legal system for liability.

  A clear and uniform definition of a low-risk trial is required and needs to take into account the extent of knowledge and prior experience with the IMP (whether or not already authorised in the EU or elsewhere), the intervention in comparison to current clinical practice and the trial population.

- **Single sponsor (Consultation item no. 15)**

  We agree with the appraisal of maintaining the concept of a single sponsor.

- **Emergency clinical trials (Consultation item no. 16)**

  We agree with the appraisal addressing this type of research and bring the regulatory framework in line with internationally agreed texts as outlined.

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- **Ensuring compliance with Good Clinical Practices in clinical trials performed in third countries (Consultation item no. 17)**

  We agree with the outlined appraisal. We strongly support increasing the transparency of clinical trials performed in third countries and limiting their acceptance for marketing authorisation purposes only if the trial has been registered in the EU clinical trials database EudraCT and published via the public EU-database EudraPharm.

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