Response from AGES PharmMed (Austria)

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Consolidated comments of AGES PharmMed to the concept paper submitted for public consultation on the REVISION OF THE 'CLINICAL TRIALS DIRECTIVE' 2001/20/EC.

Consultation item no. 1/2:

- **It is agreed that a single submission would greatly reduce the administrative work of sponsors for submission of documentation to the Member States concerned.**
- **It is agreed that separate assessment would not address the effort for more harmonization.**

Consultation item no. 3:

- **It is agreed that a central assessment is not the best option due to ethical, national, and local perspectives, the frequency of the meetings, infrastructure, and high costs. Furthermore, most trials are national or involve only a few Member States.**
- **It is agreed that a coordinated assessment procedure (CAP) involving only the Member States concerned and allowing each member state to give input is the preferred option.**

Consultation item no. 4:

- **No, the above catalogue is considered incomplete. It should define the three main areas quality, preclinical and clinical issues and refer to the specific parts of the dossier (Investigational Medicinal Product Dossier, Investigator's brochure, protocol).**

Consultation item no. 5:

- **It is agreed to include the aspects under a), and only these aspects, in the scope of the CAP.**
- **Further comment: Assessment of the Ethics Committees is not limited to "ethical issues" as described in b), but also covers preclinical and clinical aspects.**

Consultation item no. 6:

- **The approach to allow an individual Member State to "opt out", if justified, is preferred (Option 1).**

Consultation item no. 7:

- **An optional CAP (Option 3) would be preferred during the transition period; a mandatory CAP for all multinational trials (Option 2) would be preferred after expiry of the transition period**

Consultation item no. 8:

- **We do not believe that a pre-assessment, as defined by the concept paper, is workable in practice.**

Consultation item no. 9:

- **It is agreed that the definition of non-interventional trials should not be modified. Harmonised and proportionate requirements applying to all clinical trials within the scope of the Clinical Trials Directive (including non-interventional trials) are endorsed.**

Consultation item no. 10:

- **It is agreed that it is not desirable to exempt "academic/non-commercial sponsors" from the regulatory requirements of the Clinical Trials Directive. Instead, harmonised and proportionate requirements for clinical trials should be strengthened.**

Consultation item no. 11/12:

- **The approach to include sufficiently detailed provisions in Annexes to the basic legal act needs better clarification.**

Consultation item no. 13:

- **More precise clarification and harmonized interpretation of the definition of an investigational medicinal product (IMP) may be helpful. However, generating new terms such as ''Auxiliary medicinal product" may be confusing and therefore counterproductive.**

Consultation item no. 14:

- **Removal of insurance/indemnisation requirements for low-risk trials could be considered a viable option. However, responsibility for risk classification needs to be clarified. (Option 1).**

Consultation item no. 15:

- **It is preferred to maintain the concept of a single sponsor (Option 1).**

Consultation item no. 16:

- **The approach to bring the regulatory framework for the conduct of Emergency clinical trials in line with internationally-agreed texts is endorsed.**

Consultation item no. 17:

- **It is agreed that the trials should be registered in the EudraCT database. This should also be possible for already finalized clinical trials.**