International Diabetes Federation Europe

Chaussée de La Hulpe 166
BE-1170 Brussels | Belgium
Tel +32 2 5371889 | Fax +32 2 5371981
idfeurope@idf-europe.org | www.idf-europe.org

Sophie Peresson
Regional Manager
Tel +32 2 5341641
sophie.peresson@idf-europe.org

IDF Europe Response to the European Commission Public Consultation on the Review of the Clinical Trials Directive

(Directive 2001/20/EC)

Introduction

The International Diabetes Federation European Region (IDF Europe) welcomes this opportunity to contribute to the Commission's second public consultation on the assessment of the functioning of the Clinical Trials Directive (Directive 2001/20/EC). We believe the review process should have as its objective a better functioning, more proportionate and *more patient-centred* approach to the design and regulation of clinical trials.

Importantly, IDF Europe sees this review as an opportunity for reform towards more patient involvement throughout the research process. Although the Directive aimed to improve the situation of patients in relation to clinical trials, several gaps remain should be addressed in any review.

Commission concept paper

Detailed answers to public consultation questions to be found in Annex to this response.

Comments

1. Cooperation in assessing and following up applications for clinical trials

IDF Europe agrees with and supports the Commission's assessment of option 1.1- single submission with separate assessment. This option would be an ideal approach. However, even if the administrative work would be reduced, separate assessment by each Member State would remain the major problem, notably as there is a risk of biased assessments. Furthermore, IDF Europe is concerned that the European Commission may not have the capacity to manage what is needed in each Member State within a reasonable timeframe.

IDF Europe understands the Commission's preference for option 1.3- Single submission with "coordinated assessment procedure" (CAP*)* as it is ideal in theory. However, in practice, many concerns arise. There are many differences from one Member State to another and sometimes it appears virtually impossible to reach a reasonable compromise for all Member States involved in the process. This would be very time consuming and would require re-launching the process at the level of each Member State.

IDF Europe considers that disagreements with assessment reports between Member States could be resolved *by the option where* an individual Member State could be allowed to "opt out" if justified on the basis of "serious risk to public health or safety of the participant" on the basis that each Member State remains "independent". The option of the matter being referred to the Commission or the EMA for a decision at EU level could be another favourable

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option in order to avoid ultimate decisions being biased according to disclosures in some Member States.

As regards mandatory vs. optional use of the CAP, IDF Europe is in favour of the possibility where the CAP would be optional. At present, it is unknown how the CAP would work in practice and how well it takes into account the needs of the patients with different chronic diseases.

Concerning tacit approval and timelines, IDF Europe does not believe that a pre-assessment [into "low risk" and other trials] is workable in practice as it is in general terms not possible to predefine the level of the risk. Clearly, this would be very high by definition for certain compounds, but ultimately all products are potentially dangerous.

2. Better adaptation to practical requirements and a more harmonised, risk-adapted approach to the procedural aspects of clinical trials

IDF Europe agrees with the Commission's appraisal of coming up with a set of harmonised and proportionate requirements for all trials. In order to guarantee the same level of safety for all people involved in trials it is not possible to go in a different way for commercial and non-commercial trials.

IDF Europe partly agrees with more precise and risk-adapted rules for the content of the application dossier and for safety reporting listed. Due to individual reactions, the habits of taking into account different possible side-effects of the treatments, points to the need of having a broad involvement of patients in the assessments of safety issues.

Furthermore, IDF Europe is in favour of clarifying the definition of IMP and establishing rules for auxiliary medicinal products and agrees the Commissions appraisal.

With regards to insurance and indemnisation, IDF Europe is concerned by the options proposed. As regards the second option, to not have any insurance even for low risk trials seems too much of a risk for researchers/sponsors. In addition, it seems that the Commission has disregarded the possibility of an evolution of the risk category during the trail from "low-risk" to "high-risk".

IDF Europe agrees with the Commission's appraisal on Emergency clinical trials and supports maintaining the concept of a single sponsor as the only feasible option.

3. Ensuring compliance with good clinical practices in clinical trials performed in third countries

IDF Europe supports the Commissions appraisal on compliance of good clinical practice.

Concluding remarks

IDF Europe calls on the Commission to address the view of the diabetes community in the review process, with the aim of achieving a more patient-centred approach to the design and regulation of clinical trials.

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Furthermore, on a more systemic level, IDF Europe draws attention to the need for gender balance (and the necessity to represent the diversity of the targeted population) as well as the particular needs of children. Indeed a patient-centred approach should be the leading concept of every clinical trial, and so should be the revision of the directive.

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ANNEX
Public Consultation Questions Answered

1. COOPERATION IN ASSESSING AND FOLLOWING UP APPLICATIONS FOR CLINICAL TRIALS

1.1. Single submission with separate assessment

Consultation item no. 1: Do you agree with this appraisal? Please comment. Yes. This would be an ideal approach, however, even if the administrative work would be reduced – this would not solve the problems (see below). Moreover, would the Commission really be able to manage what is needed in each member state with reasonable timing?

Consultation item no. 2: Do you agree with this appraisal? Please comment. This would remain the major problem. In the assessments by separate member states there is a risk of biased assessments (clinical trials are convoyed just to certain countries). Perhaps this policy must be continued?

1.2. Single submission with subsequent central assessment

Consultation item no. 3: Do you agree with this appraisal? Please comment. We agree with the concerns mentioned above. (+ see above)

1.3. *Single submission with a subsequent 'coordinated assessment procedure'*

1.3.1. Scope of the CAP

Consultation item no. 4: Is the above catalogue complete? Yes

Consultation item no. 5: Do you agree to include the aspects under a), and only these aspects, in the scope of the CAP? Yes

1.3.2. Disagreement with the assessment report

Consultation item no. 6: Which of these approaches is preferable? Please give your reasons. A because each MS remains "independent" and C because otherwise the ultimate decision could be biased according to disclosures in some MS.

1.3.3. Mandatory/optional use

Consultation item no. 7: Which of these three approaches is preferable? Please give your reasons. C because the other procedures will just prolong the process. At the moment we do not know in practice how this suggested CAP "works" –how well it takes into account the needs of the patients with different chronic diseases.

1.3.4. Tacit approval and timelines

Consultation item no. 8: Do you think such a pre-assessment is workable in practice? Please comment. How is it possible, in general, to predefine the level of the risk? Clearly, this would be very high by definition for certain compounds, but at the end all products

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are potentially dangerous. When we are challenging people to a new treatment, a new chemical compound, it is certainly really difficult to categorize people into low and high risk.

2. BETTER ADAPTATION TO PRACTICAL REQUIREMENTS AND A MORE HARMONISED, RISK-ADAPTED APPROACH TO THE PROCEDURAL ASPECTS OF CLINICAL TRIALS

2.1. Limiting the scope of the Directive

2.1.1. Enlarging the definition of 'non-interventional' trials

Consultation item no. 9: Do you agree with this appraisal? Please comment. Yes. Unfortunately, even if the problem is real, to guarantee the same level of safety for all people involved in trials it is not possible to go in a different way for commercial and no-commercial trials.

2.1.2. Excluding clinical trials by 'academic/non-commercial sponsors' from the scope of the Clinical Trials Directive

Consultation item no. 10: Do you agree with this appraisal? Please comment.

2.2. More precise and risk-adapted rules for the content of the application dossier and for safety reporting

Consultation item no. 11: Do you agree with this appraisal? Please comment. Yes, partly. Because of Individual reactions, the habits of taking into account different possible side-effects of the treatments, points to the need of having a broad involvement of patients in the assessments of safety issues.

Consultation item no. 12: Are there other key aspects on which more detailed rules are needed? No

2.3. Clarifying the definition of 'investigational medicinal product' and establishing rules for 'auxiliary medicinal products'

Consultation item no. 13: Do you agree with this appraisal? Please comment. Yes

2.4. Insurance/indemnisation

2.4.2. Policy options

Consultation item no. 14: Which policy option is favourable in view of legal and practical obstacles? What other options could be considered? None of the proposed solutions seem to work. Options to be considered: Either to continue as it has been or then the second option =Obliging Member States..., because what happens when a risk category of a trial changes during the trial from "low-risk" to "high-risk" (option 1)? To not have any insurance even for low risk trial seems too risky for researchers/sponsors. Also, it is quite strange that a State would be keen to get the responsibility for such kind of studies.

2.5. Single sponsor

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Consultation item no. 15: Do you agree with this appraisal? Please comment. Yes. Option one is the only one possible.

2.6. Emergency clinical trials

Consultation item no. 16: Do you agree with this appraisal? Please comment. Yes

3. ENSURING COMPLIANCE WITH GOOD CLINICAL PRACTICES IN CLINICAL TRIALS PERFORMED IN THIRD COUNTRIES

Consultation item no. 17: Do you agree with this appraisal? Please comment. Yes

4. FIGURES AND DATA

Consultation item no. 18: Do you have any comments or additional quantifiable information apart from that set out in the annex to this document? If so, you are invited to submit them as part of this consultation exercise.