



Submission of the Department of Health & Children, Ireland

Revision of the 'Clinical Trials Directive' 2001/20/EC Concept Paper Submitted for Public Consultation

INTRODUCTION

The Department of Health & Children welcomes the priority which has been given by the EU Commission to review of the Clinical Trials Directive 2001/20/EC. It is important that the EU's legislative framework for the conduct of clinical trials facilitates European patients having access to treatment with new, innovative and valuable medicinal products while at the same time maintaining patient safety, fostering high-quality research and promoting the EU's competitive research environment. Revision of the Clinical Trials Directive will allow the EU to review its clinical trials regulatory framework to ensure that it is streamlined, efficient and continues to be robust in its protection of patients.

CONSULTATION TOPICS

1. Cooperation in assessing and following-up Applications for Clinical Trials

1.1 Single submission with separate assessment

With regard to Consultation items no. 1 & 2, in line with the comments of the Irish Medicines Board, the Department supports a single mechanism of submission and agrees with the concept paper's assessment that a separate assessment will not sufficiently address the difficulties arising from independent assessments.

1.2 Single submission with subsequent central assessment

As per the comments of the Irish Medicines Board, the Department agrees with the concept paper's appraisal that a central assessment would not be workable for clinical trials.

1.3 Single Submission with subsequent 'coordinated assessment procedure'

The Department is supportive of the single submission with a coordinated assessment procedure model as proposed in the concept paper and agrees that ethical issues regarding clinical trials are matters for Member States.

1.3.1 Scope of the CAP

In response to Consultation items no. 4 and 5 the Department agrees with the concept paper's proposal that ethical and local aspects should not form part of the scope of the coordinated assessment procedure.

It is noted that, on page 4, the concept paper envisages that a coordinated assessment procedure would lead to a single decision per Member State. A single decision per Member State would be desirable however; it is not clear how this can be achieved.

1.3.2 Disagreement with the assessment report

As outlined in the views of the Irish Medicines Board regarding Consultation item no. 6, where a Member State disagrees with the assessment report, it should be permitted to opt out where such a view is justified on the basis of a serious risk to public health or safety of participants.

1.3.3 Mandatory/optional use

In response to Consultation item no. 7, it is the Department's view that the CAP is the most appropriate option for all multinational clinical trials.

1.3.4 Tacit approval & timelines

As outlined in the Irish Medicines Board submission on Consultation item no. 8, the Department concurs that, as a pre-assessment stage will also require a time period for its conduct, a pre-assessment stage may not significantly reduce the time required, and if Member States were to disagree during the pre-assessment stage, this could have the effect of lengthening the process.

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 Clinical Trials Directive

2.1.1 Enlarging the definition of non-interventional trials

On Consultation item no. 9 the Department agrees with the approach proposed in the concept paper to develop harmonised and proportionate requirements which would apply to all clinical trials rather than defining non-interventional trials more broadly to exclude these from the scope of the Directive.

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

Regarding consultation item no. 10 the Department considers that trials undertaken by academic / non-commercial sponsors should also be subject to equivalent, harmonised and proportionate requirements under the Clinical Trials Directive, as the protections afforded to patients under the Directive should be equally applicable to those patients participating in academic or non-commercial trials.

2.2 More precise and risk-adapted Rules for the content of the Application Dossier and for Safety Reporting

On Consultation items no. 11 & 12 the Department supports the proposal that the guidelines be included as annexes to the Directive which may be updated from time to time by means of delegated acts.

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

On Consultation item no. 13 the Department is supportive of clarification and simplification of the rules relating to all medicinal products used in clinical trials, whether they are the investigational medicinal product or other medicinal products. The Department notes the proposals set out in the concept paper to define investigational medicinal product more broadly, while separately establishing an appropriate regulatory structure for other medicinal products used in trials.

2.4 Insurance/indemnification

The Department notes the issues raised in the concept paper relating to the insurance requirements of the Directive, and in particular that the Directive's requirements do not differentiate between differing degrees of risk associated with different clinical trials, thus having cost implications.

In response to Consultation item no. 14, the Department is concerned that the implications of imposing an obligation on Member States to indemnify all clinical trials occurring on their territory are

not fully understood. Such a proposal will have cost and budgetary implications for Member States, would necessitate significant changes to existing national frameworks and procedures, may have implications in terms of accountability and could result in responsibilities for clinical trials being essentially divested to the State.

2.5 Single sponsor

As set out in the IMB's submission, the Department also supports the concept of multiple sponsorship/'joint sponsorship' bearing in mind the points made in section 2.5.

2.6 Emergency clinical trials

The Department supports need for regulation of informed consent in emergency clinical trials and support the comments of the Irish Medicines Board regarding cognisance of the role of national ethics committees and national law in relation to informed consent.

3. Ensuring compliance with GCP in clinical trials performed in third countries

In response to Consultation item no. 17, the Department agrees with the proposals set out in this section of the concept paper and notes in particular the proposal to support capacity building with regard to clinical trials, in third countries where the regulatory framework may be weak.

4. Figures and data

On Consultation item no. 18 the Department has no additional comments.

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12 May 2011*