EUROPEAN COMMISSION

Brussels, 6.3.2013
C(2013) 1342 *final*

Mr Evangelos MEIMARAKIS
President of the
Vouli ton Ellinon
11, Av. Vassilissis Sofias
GR – 10021 ATHENS

Dear President,

The Commission would like to thank the Vouli ton Ellinion for its Opinion on the proposal for a Regulation of the European Parliament and the Council on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC {COM(2012) 369 final}.

As regards the choice of a Regulation, rather than of a revision of the existing Directive, the Commission stands by the justification provided in the explanatory memorandum of the Proposal, and would especially like to underline that, in the public consultation phase, many stakeholders highlight divergent transpositions of the current Directive as a major obstacle for the conduct of clinical trials in Europe.

The Commission furthermore remains convinced that the proposed Regulation would allow for a net reduction in administrative costs, including costs incurred by public authorities. The Commission would like to refer the Vouli ton Ellinion to the detailed analysis of the costs and burdens contained in the Commission's impact assessment report[1] and in particular Annexes III to VI. The Commission would also like to highlight that the proposal gives the possibility to Member States to set up and collect fees for the activities conducted in the framework of the assessment of clinical trials applications and for ensuring the coverage of "commercial" sponsors under the national indemnification scheme.

Concerning the selection by the sponsor of the reporting Member State, the last paragraph of Article 5(1) of the proposal foresees the possibility for the proposed reporting Member State to decline this role by agreeing with another Member State concerned. The choice indicated by the sponsor would apply only in cases where there would be no agreement between the Member States concerned. The Commission proposal aims at ensuring that one of the Member States concerned by the application would take the lead for the coordination of the assessment of aspects covered by part I.

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[1] SWD(2012) 200 final
http://ec.europa.eu/health/files/clinicaltrials/2012_07/impact_assessment_part1_en.pdf

http://ec.europa.eu/health/files/clinicaltrials/2012_07/impact_assessment_part2_en.pdf

In articles 6 and 7 of the Proposal, the Commission aims at identifying issues which are best assessed in cooperation between the Member States concerned by the clinical trial application and issues of national local or regional nature where the competence for the assessment should remain at national level. For example, rules for the protection of personal data or rules on indemnities/damage compensation, which depend on national legislation, would have to be assessed independently by each Member State. The Commission would also like to clarify that no duplicate assessment under the provisions of articles 6 and 7 is foreseen and that these two assessments should be conducted in parallel.

Concerning the possibilities for the Member States concerned to disagree with the conclusions of the report prepared by the reporting Member State, the Commission would like to stress that such a report would not be drafted only by the reporting Member State. Under the procedure proposed in Article 6, the reporting Member State would act as a coordinator and consolidator of the final report. Recognising the existence of differences in clinical practice between Member States, the Commission considers however necessary to ensure the possibility for Member States not to accept the conclusions of such a report in certain limited and appropriately justified cases.

As regards clinical trials conducted in emergency situations, the Commission would like to underline that before being initiated, such trials would have to be assessed and authorised. Furthermore, such trials would have to relate exclusively to medical conditions which make it impossible to obtain prior informed consent and, more importantly, would have to pose a minimal risk and a minimal burden to the subject.

On co-sponsorship, article 69 of the Proposal clarifies that either the sponsors define the respective responsibilities in a contract, or responsibilities should lie with all sponsors. In addition, Paragraph 2 of the same article provides for an obligation to establish a sponsor responsible for the authorisation procedure of the trial and for possible subsequent modifications, acting as a contact point for subjects, investigators and Member States and implementing corrective measures imposed by Member States.

Finally, as regards the establishment of a national indemnification mechanism, the Commission would like to highlight the possibility given by the last paragraph of article 73(3) to establish a fee for "commercial" clinical trials to join such mechanism. Articles 71 and 72 clarify that the rules on compensation and liability remain subject to the national applicable laws.

The Commission hopes that these clarifications address the comments and concerns raised by the Vouli ton Ellnion and looks forward to continuing our political dialogue in the future.

Yours faithfully,

Maroš Šefčovič
Vice-President