EUROPEAN COMMISSION

Brussels, 20.02.2013
C(2013) 663 *final*

Dear President,

The Commission would like to thank the Assembleia da República 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}.

The Commission would like to make the following remarks on the comments provided by the Assembleia da República.

Concerning the choice of the form of a Regulation, on top of the explanation provided in the explanatory memorandum, the Commission would like to highlight that the divergent transpositions of the current Directive have been mentioned by several stakeholders in the consultation process carried out in the preparation of the current proposal as a major obstacle for the conduct of cross-border clinical trials in Europe.

Concerning the timelines for the authorisation of an application for the conduct of a clinical trial, the Commission would like to underline that the timeline of six days referred to in the opinion of the Assembleia da República (article 5(2) of the proposal), concerns only the validation of an application submitted. The assessment and the decision phase, and their timeline, are described in Articles 6-10 of the proposal. In summary, for a "normal" clinical trial, the proposed timeline for the authorisation of an application would be of 41 days. This timeline could be further extended if contacts with the sponsor in view of obtaining further information or clarifications are necessary.

The Commission hopes that these clarifications address the comments and concerns raised by the Assembleia da República and looks forward to continuing our constructive political dialogue in the future.

Yours faithfully,

Maroš Šefčovič
Vice-President

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