EUROPEAN COMMISSION

Brussels, 21. 02 .2013
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Dear President,

The Commission would like to thank the Senát 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 is convinced that the proposal does not interfere with the right of Member States to define their health policies and the organisation of their health systems as stipulated by the Treaty and, at the same time, recognises existing different clinical practices. Indeed, Article 8 (2) of the proposal foresees that should a Member State disagree with the joint assessment of an application for the authorisation of a clinical trial because of differences in normal clinical practice which would lead the patients to receive an inferior treatment, it may opt out and not authorise the conduct of the trial on its territory. That Member State should justify such an opt out. The Commission would like to stress that these justifications may be based not only on scientific but also on socio-economic reasons.

The Commission proposal in no way aims at abolishing ethics committees. On the contrary, Article 9 of the proposal defines the characteristics of the persons assessing the applications (in particular they should be independent and have the necessary qualifications and experiences), in line with the definition of an ethics committee provided by paragraph 15 of the Declaration of Helsinki. However, as currently the responsibilities, and even the names, of the so called "ethics committees" vary widely between the different Member States, the Commission has chosen not to interfere with the internal organisation of the Member States on the bodies responsible and on their responsibilities for the assessment of a clinical trial application.

Finally, the Commission considers that the procedure for the authorisation of clinical trials, including the tacit agreement procedure, is an important element to improve the competitiveness of the EU for clinical research while it does not compromise the protection of the right of the subjects participating in a clinical trial and ensures that the timelines for the assessment are respected.

Mr Milan ŠTĚCH
President of the Senate of the Parliament of the Czech Republic
Valdštejnské naměstí 17/4
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PRAGUE 1

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

Yours faithfully,

Maroš Šefčovič
Vice-President