



## EUROPEAN COMMISSION

Brussels, 21.02.2013  
C(2013) 668 final

*Dear President,*

*The Commission would like to thank the Senato della Repubblica 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 Senato della Repubblica expressed concerns about the compatibility of the proposed timelines for the assessment of an application for a clinical trial authorisation with the current operational procedures of the competent authorities and the ethical committees. The Commission would like to underline that appropriate transitional periods for the applications of the new rules are laid down in articles 91 and 92 of the proposal.*

*The Senato della Repubblica's suggestions to allow:*

- *the national regulatory authorities to recognise therapeutic indications which have been validated by independent clinical trials;*
- *independent studies to be taken into consideration for registration purposes;*
- *the possibility for the competent regulatory authorities to grant therapeutic indications for treatments which have been experimentally validated by academic researchers, through independent, non-commercial studies, irrespective of the intentions or interests of the company which holds the authorisation to market the product;*

*are related primarily to the marketing authorisation process for medicines rather than to the authorisation process and conduct of clinical trials. However, the Commission would like to stress that the proposal aims at streamlining the authorisations and the follow up of clinical trials while ensuring the highest possible level of protection of the safety and rights of subjects and the robustness of the data collected.*

*Mr Renato SCHIFANI  
President of the  
Senato della Repubblica  
Piazza Madama, 1  
IT – 00186 ROMA*

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

*Yours faithfully,*

*Maroš Šefčovič  
Vice-President*