SENATE OF THE ITALIAN REPUBLIC

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RESOLUTION OF STANDING COMMITTEE 12
(Hygiene and Health)

(*Rapporteurs*: COSENTINO *and* D'AMBROSIO LETTIERI)

adopted at the sitting of 25 September 2012

CONCERNING THE

PROPOSAL FOR A REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL ON CLINICAL TRIALS ON MEDICINAL PRODUCTS FOR HUMAN USE, AND REPEALING DIRECTIVE 2001/20/EC
(COM(2012) 369 final)

pursuant to Article 144(1) and (6) of the Rules of Procedure

Communicated to the Office of the Prime Minister on 28 September 2012

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The Committee:

– having examined Community document (COM(2012) 369 final) containing the proposal for a regulation of the European Parliament and of the Council on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001;

– whereas the reason for the proposal in question is that the European Commission considers that Directive 2001/20/EC (which has, indeed, brought about important improvements in the safety and ethical soundness of clinical trials in the EU and in the reliability of clinical trials data) must be replaced on account of the criticisms from patients, industry, and academic research and also on account of the fall in the number of applications, the increase in the cost of conducting clinical trials and the increase in the average delay for launching a clinical trial;

– having regard to the outcome of the hearings held at the informal sitting of 12 September 2012;

1. Expresses its view in favour, in accordance with Protocol (No 2) to the Treaty on the Functioning of the European Union on the application of the principles of subsidiarity and proportionality. It considers that the proposal complies with the principle of subsidiarity in terms of a need for action by the Union institutions: only a regulation can ensure Union-wide consistency in the procedures for conducting clinical trials of medicinal products for human use. The proposal also represents added value for the Union by virtue of the enhanced quality and safety of medicinal products, stemming from the increased reliability of clinical trials data, that it is hoped it will bring about.

With regard to compliance with the principle of proportionality, the proposal is consistent with the objectives that it seeks to attain.

2. Expresses its view in favour with regard to the content of the act under consideration, observing that there is a need to strike an appropriate balance between the removal of bureaucratic delays and obstacles arising from the current rules and the interest in having an assessment of the effective safety of clinical trials. In this connection, where the assessment procedure which will be implemented at national level is concerned, it suggests a careful examination of the compatibility of very tight assessment timescales with the operational procedures of the competent authorities and the ethical committees; a reasonable transitional period should be allowed for the implementation of the provisions which will replace the previous Directive 2001/20/EC.

In particular, where the competent authorities are concerned it is essential to channel appropriate resources into strengthening the cooperation between the *Agenzia Italiana del Farmaco* (AIFA – Italian Medicines Agency) and the *Istituto Superiore di Sanità* (Higher Institute of Health), which has always had the role of authorising phase I studies. Where the ethics committees are concerned, meanwhile, in view of the need for a

reduction in their number it would be advisable to establish very swift operating procedures on the basis of weekly meetings and purely electronic operations.

With regard to the criteria for identifying the ethics committees and the number thereof, what should be taken into account is the quality and quantity of clinical trials, as periodically updated and reported by the National Observatory on Clinical Trials and Ethics Committees established within AIFA, and the population data.

Finally, with regard to the national indemnification mechanism introduced by Article 73 for compensating damage arising from clinical trials other than low-intervention trials, the establishment of an ad hoc fund, managed together with public social security institutions, should be considered.

3. Provision should be made for the possibility of allowing the national regulatory authorities to recognise therapeutic indications which have been validated by independent clinical trials, and of exerting pressure at EU level (Commission, Council, European Parliament) for (a) independent studies to be taken into consideration for registration purposes; and (b) of allowing the competent regulatory authorities the option of granting 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.

OPINION OF STANDING COMMITTEE 2
(LEGAL AFFAIRS)

(Rapporteur: CHIURAZZI)

18 September 2012

The Committee, having examined document COM(2012) 369 final, issues a favourable opinion, within its area of responsibility.