



THE PARLIAMENT OF THE CZECH REPUBLIC

SENATE

8th TERM

781st RESOLUTION

delivered on the 26th meeting held on 26th October 2012

on the Proposal for a regulation of the European Parliament and of the Council on clinical trials on medical products for human use, and repealing Directive 2001/20/EC /Senate Press no. N 175/08/

The Senate

- I.**
- 1. Supports**
the European Union's initiative to facilitate the launching of clinical trials of medical products for human use;
 - 2. Highlights**
the absolute necessity of protection of life and health of test subjects and workers who take part in all forms of clinical trials;
 - 3. Reminds**
that Article 168 of the Treaty on the functioning of the European Union recognizes the responsibility of the Member States for their health policies and for the organization and supply of health care, the role of the EU in this area being limited to support of the Member States' initiatives;
- II.**
- 1. Requests**
the European Union to better define the key concept of infringement of common clinical practice in the authorisation process of clinical trials;
 - 2. Recommends**
that the role of ethical panels as an important authority assessing the applications for initiation of clinical trials is taken into account in the proposal;
 - 3. Requests**
to include issues relating to ethical, cultural and social aspects of a clinical trial amongst those grounds based on which a Member State may refuse to initiate a clinical trial;
 - 4. Disagrees**
with the proposed concept of fiction of consent, i.e. with the automatic assumption that once a Member State had not notified the sponsor of a motion to initiate a clinical trial within the substantially reduced time period, it is believed that this Member State does not object to the initiation of the clinical trial;
- III.**
- 1. Requests**
the Government to inform the Senate about the way this position was taken into account and to provide the Senate with information on the further proceeding of negotiations;

2. Authorises

the President of the Senate to forward this Resolution to the European Commission.

Milan Štěch
sign manual
President of the Senate

Miroslav Škaloud
sign manual
Senate Verifier