JOINT SESSION

- **SPECIAL STANDING COMMITTEE FOR EUROPEAN AFFAIRS**

STANDING COMMITTEE FOR PRODUCTION AND TRADE

The aforementioned Committees of the Hellenic Parliament came to a joint session on October 10th 2012 , in order to adopt an

OPINION

On 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

The members of the aforementioned Committees , having considered:

- The Proposal's text
- The informational note by the Greek National Organization for Medicines
- The oral briefing by the Alternate Minister for Health, Mr. Marios Salmas
- The oral briefing by the Chairman of the National Organization's for Medicines Administrative Council, Professor Mr. Ioannis Tountas

Adopted by majority the following opinion:

Subsidiarity Principle

The Proposal for a regulation repeals **Directive 2001/20/EC** on the process of authorizing and carrying out clinical trials on medicinal products for human use. The issue of marketing authorization of a certain medicine falls within the scope of article 168 par. 4 p.c of the TFEU on the taking of measures for specifying high quality and security standards for medicinal products and medical equipment . However, the clinical trial area is conceptually directly associated to each member-state's intrinsic ethics and code of conduct on an individual basis (subject protection, emergency situations, patients' associations' codes), and , therefore, internal regulation by national structures and laws is deemed as more correct. In this sense, revision of

existing legislation by means of a new Directive and not by Regulation is deemed as more appropriate.

Proportionality Principle

By extent, the Proposal for Regulation presents problems concerning the proportionality principle, as going beyond what is necessary for achieving its objective. The proposed Regulation's provisions (member-state reporting obligation duties, by sponsor's recommendations, obligation of member-states to set up a national indemnification mechanism etc) entail disproportionate costs for member-states, whereas the objective of encouraging research in Europe may be regulated via a revised directive.

Remarks-comments

Regarding specific points in the proposed Regulation's text, our remarks are the following:

1. According to (EU portal) procedures described in Article 5 of the proposed Regulation, an obligation arises for a proposed by the sponsor member-state to become a reporting member-state. The aforementioned obligation resulting from article 5 entails excessive time, material, technical, economic and administrative costs, also given the important member-states' dimension at the level of readiness, availability and experience.
2. According to articles 6-7 of the proposed regulation, assessment duties of the application's aspects are shared by the reporting member-state and each member-state concerned. Assessment of the research file aspects, such as legal, ethical issues and considerations regarding the subject's protection, protection of personal data, indemnity or researchers' fees, by each member-state concerned , practically negates the advantages (time and cost saving) that could be brought about by the application's part assessment , exclusively by the reporting member-state.
3. Article 8 treats the terms and conditions- on part of member-state concerned- regarding acceptance or non-acceptance of clinical trial conduct by the reporting member-state However, grounds for disagreement listed are broad

enough to base a wide variety of objections by member-states concerned, to a degree that this would become a practice (rule).

4. Regarding clinical trials in emergency situations (article 32), it is possible that, in certain member-states the obtainment of informed consent by the subject or their legal representative after the start of the clinical trial shall be judged as opposing to accepted principles of morality and as being against public order, since the result in case of a not-assessed risk (such as the case of clinical trial), shall be irreversible.
5. The introduction of the “co-sponsor” concept may be a source of confusion regarding competences’ and responsibilities’ distribution between sponsors, and ensuing legal uncertainties.
6. Articles 72 and 73 of the proposed Regulation treat the issue of damage compensation in cases of additional risk or potential damage, as well as the issue of establishing a national indemnification mechanism. Although this solution facilitates insurance coverage of subjects for non-commercial sponsors, it brings about additional administrative and economic burden to member-states, taking also into account litigations that will certainly arise.