Question for written answer E-011331/2012
to the Commission
Rule 117
Petru Constantin Luhan (PPE)

Subject: Need for a provision in the protocol of clinical trials

Further to the Commission's answer of 5 November 2012 to Written Question E-008806/2012, and bearing in mind that the early termination of a clinical trial alters the risk-benefit ratio initially envisaged in the trial protocol, can the Commission answer the following questions in relation to its proposal for a regulation COM(2012)0369:

What is the Commission's view on the introduction of a provision in the proposal for a clinical trials regulation concerning the mandatory setting-out of the measures that must be taken by sponsors in the event of the early termination of the clinical trial?

Does the Commission consider it an ethical requirement that patients who may be included in the trial should be made aware of their situation in the event of its early termination, before giving their informed consent?