

SENATE OF THE REPUBLIC  
17th PARLIAMENTARY TERM

Doc. XVIII No 21

**RESOLUTION OF THE 12TH STANDING COMMITTEE**

(Hygiene and Health)

(Rapporteur: Bianconi)

approved at the session of 18 September 2013

ON

**THE PROPOSAL FOR A DECISION OF THE EUROPEAN PARLIAMENT AND  
OF THE COUNCIL ON THE PARTICIPATION OF THE UNION IN A SECOND  
EUROPEAN AND DEVELOPING COUNTRIES CLINICAL TRIALS  
PARTNERSHIP PROGRAMME JOINTLY UNDERTAKEN BY SEVERAL  
MEMBER STATES (COM(2013) 498 FINAL)**

In accordance with Article 144(1) and (6) of the Rules of Procedure

Notified to the President's Office on 3 October 2013

17th PARLIAMENTARY TERM - DRAFT LEGISLATION AND REPORTS -  
DOCUMENTS

The Committee,

having examined the proposal for a Decision of the European Parliament and of the Council of 10 July 2013 on the participation of the Union in a second European and Developing Countries Clinical Trials Partnership Programme jointly undertaken by several Member States (COM(2013) 489 final);

having noted that the above proposal relates, in particular, to the participation of the European Union in the second phase of the European and Developing Countries Clinical Trials Partnership Programme (EDCTP 2), aimed at developing more effective medical interventions (products, treatments and vaccines) for the three main poverty-related diseases (HIV/AIDS, malaria and tuberculosis); and that the action will be undertaken for the benefit of and in partnership with developing countries, particularly those in sub-Saharan Africa;

considering that the EU act concerned has its legal basis in Article 185 of the Treaty on the Functioning of the European Union (TFEU), which lays down that 'In implementing the multiannual framework programme, the Union may make provision, in agreement with the Member States concerned, for participation in research and development programmes undertaken by several Member States, including participation in the structures created for the execution of those programmes';

having noted that the proposal is in line with Decision No 1209/2003/EC of the European Parliament and of the Council of 16 June 2003 on Community participation in a research and development programme aimed at developing new clinical interventions to combat HIV/AIDS, malaria and tuberculosis through a long-term partnership between Europe and developing countries, undertaken by several Member States under the acronym EDCTP from 2003 to 2012;

having regard to the advisability of comprehensively enhancing the full set of tools in the fight against poverty-related diseases, including preventive interventions;

issues, in accordance with Protocol 2 to the Treaty on the Functioning of the European Union 'On the application of the principles of subsidiarity and proportionality',

a favourable opinion on observance of the principle of subsidiarity, taking into account that: there is a need for intervention by the institutions of the Union to achieve what the European Commission calls 'the required critical mass, both in human and financial terms, by bringing together available complementary expertise and resources to accelerate the development of new or improved medical interventions' to reduce the devastating impact of diseases related to poverty; this creates appreciable added value for the Union in terms of: greater cost-effectiveness of European investments in clinical research programmes, establishing a common platform that allows research results to be put to better use; the long-term structuring effect on European and developing countries' research policies, helping to integrate the EU's research and development policies and systems into a coherent context.

a favourable opinion on observance of the principle of proportionality as the proposal appears to be consistent with the objectives it aims to achieve;

hereby issues a favourable opinion, with the following observation:

that, in addition to clinical studies aimed at developing treatments, consideration be given to the value of research into preventing poverty-related diseases.