

Wednesday 2 April 2014

P7_TA(2014)0273

Clinical trials on medicinal products for human use *I**

European Parliament legislative resolution of 2 April 2014 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)0369 — C7-0194/2012 — 2012/0192(COD))

(Ordinary legislative procedure: first reading)

(2017/C 408/22)

The European Parliament,

- having regard to the Commission proposal to Parliament and the Council (COM(2012)0369),
 - having regard to Article 294(2) and Articles 114 and 168(4) of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0194/2012),
 - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
 - having regard to the reasoned opinion submitted, within the framework of Protocol No 2 on the application of the principles of subsidiarity and proportionality, by the Polish Sejm, asserting that the draft legislative act does not comply with the principle of subsidiarity,
 - having regard to the opinion of the European Economic and Social Committee of 12 December 2012 ⁽¹⁾,
 - after consulting the Committee of the Regions,
 - having regard to the undertaking given by the Council representative by letter of 20 December 2013 to approve Parliament's position, in accordance with Article 294(4) of the Treaty on the Functioning of the European Union,
 - having regard to Rule 55 of its Rules of Procedure,
 - having regard to the report of the Committee on the Environment, Public Health and Food Safety and the opinions of the Committee on Industry, Research and Energy, the Committee on the Internal Market and Consumer Protection and the Committee on Civil Liberties, Justice and Home Affairs (A7-0208/2013),
1. Adopts its position at first reading hereinafter set out;
 2. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;
 3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

P7_TC1-COD(2012)0192

Position of the European Parliament adopted at first reading on 2 April 2014 with a view to the adoption of Regulation (EU) No .../2014 of the European Parliament and of the Council on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC

(As an agreement was reached between Parliament and Council, Parliament's position corresponds to the final legislative act, Regulation (EU) No 536/2014.)

⁽¹⁾ OJ C 44, 15.2.2013, p. 99.