

**European Medicines Agency (conduct of pharmacovigilance activities in respect of medicinal products for human use)\*\*\*I**

**European Parliament legislative resolution of 16 April 2014 on the proposal for a regulation of the European Parliament and of the Council on fees payable to the European Medicines Agency for the conduct of pharmacovigilance activities in respect of medicinal products for human use (COM(2013)0472 – C7-0196/2013 – 2013/0222(COD))**

**(Ordinary legislative procedure: first reading)**

*The European Parliament,*

- having regard to the Commission proposal to Parliament and the Council (COM(2013)0472),
  - having regard to Article 294(2) and Articles 114 and 168(4)(c) of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0196/2013),
  - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
  - having regard to the reasoned opinions submitted, within the framework of Protocol No 2 on the application of the principles of subsidiarity and proportionality, by the Greek Parliament and the Spanish Congress of Deputies and the Spanish Senate, 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 16 October 2013<sup>1</sup>,
  - after consulting the Committee of the Regions,
  - having regard to the undertaking given by the Council representative by letter of 19 February 2014 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 (A7-0476/2013),
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.

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<sup>1</sup> OJ C 67, 6.3.2014, p. 92..

**P7\_TC1-COD(2013)0222**

**Position of the European Parliament adopted at first reading on 16 April 2014 with a view to the adoption of Regulation (EU) No .../2014 of the European Parliament and of the Council on fees payable to the European Medicines Agency for the conduct of pharmacovigilance activities in respect of medicinal products for human use**

*(As an agreement was reached between Parliament and Council, Parliament's position corresponds to the final legislative act, Regulation (EU) No 658/2014.)*