

P7_TA(2012)0313

Pharmacovigilance (amendment of Directive 2001/83/EC) *I**

European Parliament legislative resolution of 11 September 2012 on the proposal for a directive of the European Parliament and of the Council amending Directive 2001/83/EC as regards pharmacovigilance (COM(2012)0052 – C7-0033/2012 – 2012/0025(COD))

(Ordinary legislative procedure: first reading)

The European Parliament,

- having regard to the Commission proposal to Parliament and the Council (COM(2012)0052),
 - having regard to Article 294(2), Article 114 and Article 168(4)(c) of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0033/2012),
 - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
 - having regard to the opinion of the European Economic and Social Committee of 28 March 2012¹,
 - after consulting the Committee of the Regions,
 - having regard to the undertaking given by the Council representative by letter of 27 June 2012 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 (A7-0165/2012),
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 the 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.

¹ OJ C 181, 21.6.2012, p. 201.

P7_TC1-COD(2012)0025

Position of the European Parliament adopted at first reading on 11 September 2012 with a view to the adoption of Directive 2012/.../EU of the European Parliament and of the Council amending Directive 2001/83/EC as regards pharmacovigilance

(As an agreement was reached between Parliament and Council, Parliament's position corresponds to the final legislative act, Directive 2012/26/EU.)