P7_TA(2010)0331

Pharmacovigilance of medicinal products (amendment of Regulation (EC) No 726/2004) ***I

European Parliament legislative resolution of 22 September 2010 on the proposal for a regulation of the European Parliament and of the Council amending, as regards pharmacovigilance of medicinal products for human use, Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (COM(2008)0664 – C6-0515/2008 – 2008/0257(COD))

(Ordinary legislative procedure: first reading)

The European Parliament,

– having regard to the Commission proposal to the European Parliament and the Council (COM(2008)0664),

– having regard to Article 251(2) and Article 95 of the EC Treaty, pursuant to which the Commission submitted the proposal to Parliament (C6-0515/2008),

– having regard to the Communication from the Commission to the European Parliament and the Council entitled "Consequences of the entry into force of the Treaty of Lisbon for ongoing interinstitutional decision-making procedures" (COM(2009)0665),

– having regard to Article 294(3) and Article 114 and Article 168(4)(c) of the Treaty on the Functioning of the European Union,

– having regard to the opinion of the European Economic and Social Committee of 10 June 2009[1],

– having regard to the opinion of the Committee of the Regions of 7 October 2009[2],

– having regard to the undertaking given by the Council representative by letter of 23 June 2010 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 and the Committee on the Internal Market and Consumer Protection (A7-0153/2010),

1. Adopts its position at first reading hereinafter set out;

2. Takes note of the Commission statement annexed to this resolution;

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1 OJ C 306, 16.12.2009, p. 22.
2 OJ C 79, 27.3.2010, p. 50.

3. 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;

4. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

P7_TC1-COD(2008)0257

Position of the European Parliament adopted at first reading on 22 September 2010 with a view to the adoption of Regulation (EU) No .../2010 of the European Parliament and of the Council amending, as regards pharmacovigilance of medicinal products for human use, Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, and Regulation (EC) No 1394/2007 on advanced therapy medicinal products

(As an agreement was reached between Parliament and Council, Parliament's position corresponds to the final legislative act, Regulation (EU) No 1235/2010.)

ANNEX

Statement by the Commission

Following the request made by the European Parliament and the Council on the grading of the head of the European Medicines Agency, the Commission in order not to delay the adoption of this important proposal undertakes to re-publish the vacancy notice for the next head of the European Medicines Agency with the grade AD15 instead of AD14.

The Commission considers that the right place to deal with the issue is the ongoing horizontal discussion on the role of EU agencies within the Inter-institutional working group on agencies. The discussion on this aspect is open in the inter-institutional working group, and if this discussion leads to different conclusions on the appropriate publication level, then this grading could be reconsidered for future publications.