

Community code relating to medicinal products for human use: implementing powers of the Commission

2006/0295(COD) - 11/03/2008 - Final act

PURPOSE: to amend Directive 2001/83/EC on the Community code relating to medicinal products for human use, by introducing a reference to the new regulatory procedure with scrutiny (comitology).

LEGISLATIVE ACT: Directive 2008/29/EC of the European Parliament and of the Council amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the implementing powers conferred on the Commission.

CONTENT: to recall, Council Decision 1999/468/EC laying down the procedures for the exercise of implementing powers conferred on the Commission has been amended by Council Decision 2006/512/EC ([CNS/2002/0298](#)).

The amended Decision introduces a new *regulatory procedure with scrutiny* to be used for measures of general scope which seek to amend non-essential elements of a basic instrument, adopted under co-decision. This may include deleting some of those elements or supplementing the instrument, by the addition of new non-essential elements.

This procedure allows the legislator to oppose the adoption of "quasi-legislative" measures implementing a codecision-based instrument in cases where:

- the draft may exceed the implementing powers provided for in the basic instrument;
- the draft is incompatible with the aim or the content of that instrument; or
- the draft fails to respect the principles of subsidiarity or proportionality.

In a joint statement, the three institutions agreed on a list of 26 basic instruments already in force to be adjusted without delay in accordance with the new regulatory procedure with scrutiny (see [ACI/2006/2152](#)). Each case has been assessed on the nature of the implementing powers conferred on the Commission and the specificity of each sector.

The purpose of this act, therefore, is to amend EU legislation relating to medicinal products for human use, by introducing the new *regulatory procedure with scrutiny*.

ENTRY INTO FORCE: 21 March 2008.