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

2006/0295(COD) - 22/12/2006 - Legislative proposal

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).

PROPOSED ACT: Directive of the European Parliament and of the Council.

CONTENT: 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, including by deleting some of those elements or by 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 when it considers that the draft exceeds the implementing powers provided for in the basic instrument, or that the draft is incompatible with the aim or the content of that instrument or 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 its own merits, notably in view of the nature of the implementing powers conferred on the Commission and the specificity of each sector.

Lastly, in accordance with the abovementioned statement, the Commission is proposing to repeal any provisions of these instruments that provide for a time-limit on the delegation of implementing powers to the Commission.