

Colouring matters for medicinal products. Recast

2008/0001(COD) - 23/04/2009 - Final act

PURPOSE: to recast Directive 78/25/EEC on the approximation of the laws of the Member States relating to the colouring matters which may be added to medicinal products.

LEGISLATIVE ACT: Directive 2009/35/EC of the European Parliament and of the Council on the colouring matters which may be added to medicinal products (recast).

CONTENT: having reached agreement with the Parliament at first reading, the Council recasts and adapts Council Directive 78/25/EEC of 12 December 1977 on the approximation of the laws of the Member States relating to the colouring matters which may be added to medicinal products has been initiated by the Commission. The new Directive was to have superseded the various acts incorporated in it.

In the meantime, Council Decision 1999/468/EC which lays down the procedures for the exercise of implementing powers conferred on the Commission (comitology) has been amended by Decision 2006/512/EC, which introduced a regulatory procedure with scrutiny for measures of general scope designed to amend non-essential elements of a basic instrument adopted in accordance with the codecision procedure.

Consequently, the codification of Directive 78/25/EEC has been transformed into a recast in order to incorporate the amendments necessary for the adjustment to the regulatory procedure with scrutiny.

The new Directive empowers the Commission to amend the limited period of use of medicinal products following the regulatory procedure with scrutiny.

ENTRY INTO FORCE: 20/05/2009.