

Colouring matters for medicinal products. Recast

2008/0001(COD) - 11/01/2008 - Legislative proposal

PURPOSE: recast of the 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.

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

CONTENT: the codification of 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 The new Directive was to have superseded the various acts incorporated in it.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.

In accordance with the joint statement of the European Parliament, the Council and the Commission on Decision 2006/512/EC, for this new procedure to be applicable to instruments adopted in accordance with the codecision procedure, those instruments must be adjusted in accordance with the applicable procedures.

It is therefore appropriate to transform the codification of Directive 78/25/EEC into a recast in order to incorporate the amendments necessary for the adjustment to the regulatory procedure with scrutiny.