



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 19-VIII-2005
C(2005) 3256

NOT FOR PUBLICATION

COMMISSION DECISION

of 19-VIII-2005

concerning the placing on the market, under Article 31 of Directive 2001/83/EC of the European Parliament and of the Council, of the medicinal products for human use which contain the active substance Atomoxetine, Citalopram, Escitalopram, Fluoxetine, Fluvoxamine, Mianserine, Milnacipran, Mirtazapine, Paroxetine, Reboxetine, Sertraline and Venlafaxine

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(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use¹, and in particular Article 34(1) thereof,

Having regard to the opinion of 21/IV/2005 of the European Medicines Agency, formulated by the Committee for Medicinal Products for Human Use, whose opinion was requested on 17/XII/2004,

Whereas:

(1) Medicinal products for human use authorised by the Member States must meet the requirements of Directive 2001/83/EC.

(2) A scientific assessment, the conclusions of which are set out in the Annex to this Decision, has shown that, in the interest of the community, a decision should be taken to amend the marketing authorisation of the medicinal products concerned.

(3) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Medicinal Products for Human Use,

¹ OJ L 311, 28.11.2001, p. 67. Directive as last amended by [Directive 2004/27/EC (OJ L 136, 30.4.2004, p. 34)].

HAS ADOPTED THIS DECISION:

Article 1

The Member States referred to in Article 4 shall amend national marketing authorisations for the medicinal products listed in Annex I on the basis of the scientific conclusions set out in Annex II.

Article 2

The national marketing authorisations referred to in Article 1 are based on the amendments to the relevant sections of the Summary of Product Characteristics and Package Leaflets, set out respectively in Annexes III and IV.

Article 3

Under Article 34(3) of Directive 2001/83/EC, the Member States referred to in Article 4 shall comply with this Decision within thirty days of its notification.

They shall forthwith inform the Commission and the European Medicines Agency thereof.

Article 4

This Decision is addressed to the Kingdom of Belgium, the Czech Republic, the Kingdom of Denmark, the Federal Republic of Germany, the Republic of Estonia, the Hellenic Republic, the Kingdom of Spain, the French Republic, the Ireland, the Italian Republic, the Republic of Cyprus, the Republic of Latvia, the Republic of Lithuania, the Grand Duchy of Luxembourg, the Republic of Hungary, the Republic of Malta, the Kingdom of the Netherlands, the Republic of Austria, the Republic of Poland, the Portuguese Republic, the Republic of Slovenia, the Slovak Republic, the Republic of Finland, the Kingdom of Sweden, the United Kingdom of Great Britain and Northern Ireland.

Done at Brussels, 19-VIII-2005

For the Commission
Günter VERHEUGEN
Member of the Commission