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Questions and answers on generic escitalopram-containing medicines (tablets containing escitalopram oxalate, 5, 10, 15 and 20 mg)[1]

Outcome of a procedure under Article 30 of Directive 2001/83/EC

The European Medicines Agency has completed a review of a group of generic escitalopram-containing medicines that were authorised via a decentralised procedure. The Agency's Committee for Medicinal Products for Human Use (CHMP) has noted that there is a need to harmonise the decisions taken in European Union (EU) Member States involved in this decentralised procedure[2] on whether to maintain or suspend the marketing authorisations of these medicines. The CHMP concluded that marketing authorisations for the medicines should be suspended.

What is escitalopram?

Escitalopram is an antidepressant used to treat major depressive episodes. These are periods of depressed mood. Escitalopram is a 'selective serotonin reuptake inhibitor' (SSRI). It works by preventing the neurotransmitter serotonin from being taken back up into nerve cells in the brain and spinal cord. Neurotransmitters are chemicals that transfer chemical signals from one nerve cell to another. Low levels of serotonin in the central nervous system are thought to be associated with depression or anxiety.

Some generic medicines containing escitalopram have been authorised based on their similarity to the reference medicine Cipramil, which contains a mixture of escitalopram and its 'enantiomer' (a molecule with the same atoms arranged in a slightly different way so that it is a mirror image of escitalopram). The authorisations were granted as part of a 'decentralised procedure': one Member State (the 'reference Member State', in this instance the Netherlands) granted an authorisation that was valid in this country as well as in other Member States (the 'concerned Member States', in this instance

[1] Applies only to generic escitalopram-containing medicines of the following companies: Alfred Tiefenbacher GmbH & Co. KG, Centrafarm Services B.V, CT-Arzneimittel GmbH, Hexal AG, Ratiopharm GmbH, Ratiopharm Nederland B.V., Sandoz B.V. and Winthrop Arzneimittel GmbH authorised via a decentralised procedure with the Netherlands as reference Member State.
[2] Austria, Belgium, Germany, Hungary, Lithuania, Luxembourg, the Netherlands, Portugal, Slovenia and the United Kingdom.

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Austria, Belgium, Germany, Hungary, Lithuania, Luxembourg, the Netherlands, Portugal, Slovenia and the United Kingdom).

These medicines are available under the following trade names: Escitaburg, Escitafloc, Escitaham, Escitalobene, Escitalis, Escitalodeon, Escitalofi, Escitalopram, Escitalopram-1A, Escitalopram AbZ, Escitalopram Beta, Escitalopram CF, Escitalopram-CT, Escitalopram Ecitrix, Escitalopram Hexal Escitalopram Ratiopharm, Escitalopram Sandoz, Escitalopram Stada, Escitalopram Tiefenbacher, Escitalopram Winthrop, Escitatifi and Kapistrol.

Why were these escitalopram-containing medicines reviewed?

In April 2009, the Dutch medicines regulatory agency suspended the marketing authorisation of these medicines in the Netherlands as some of the data that were used to support their applications was considered to still be protected 'under data exclusivity'. As the medicines were still authorised in the other Member States, the United Kingdom medicines regulatory agency referred the matter to the CHMP for an opinion on whether the authorisations should be maintained or suspended in all the Member States involved in the decentralised procedure.

What are the conclusions of the CHMP?

The CHMP evaluated the data that was not considered to be protected under the data exclusivity rules, and concluded that there was insufficient evidence to show that the generic medicines had comparable effectiveness and safety as the reference medicine. Based on this, the Committee recommended that marketing authorisations for these medicines should be suspended.

A European Commission decision on this opinion will be issued in due course.

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