



Implementation of warnings on suicidal thoughts and behaviour in antidepressants

Companies that hold authorisations for antidepressant products will shortly be receiving letters requesting Type II variations to update the warnings on suicidal thoughts and behaviour in line with European agreements. Authorisation holders should submit the applications no later than 3 March 2008.

Background

The Pharmacovigilance Working Party (PhVWP) has considered the results of a meta-analysis of adult clinical trial data for SSRIs and other antidepressants recently completed by the FDA. The drugs included in the FDA review were bupropion, citalopram, duloxetine, escitalopram, fluoxetine, fluvoxamine, mirtazapine, nefazodone, paroxetine, sertraline and venlafaxine. The PhVWP considered the review performed by the FDA was of high quality and although it did not provide evidence to suggest that the use of SSRIs and related depressants leads to an increased risk of suicidality in the general adult population, it found a clear age effect with younger age groups having higher odds ratio estimates than older age groups. The results of the review found no marked differences in terms of risk of suicidal thoughts/behaviour across the different antidepressant classes. In the light of the results of the FDA review the PhVWP agreed that the 'EU core SPC for SSRIs and related substances' of October 2005 should be modified with regard to suicidality and should now be extended to cover all antidepressants. In particular, the wording should be updated with respect to the increased risk to young adults and the need for close monitoring of patients, and it will be applicable to all antidepressants, not only SSRIs.

The wording has been agreed at an EU level in consultation with MA holders for brand leader products and industry associations. The timetable for implementation has also been agreed at European level to ensure that healthcare professionals, patients and their carers receive this important safety information as soon as possible.

Amendments required

The agreed wording can be found as a download document at the end of this page.

Further information

Further information on the scientific basis of this regulatory action and questions and answers on the procedure for updating SPCs and PLs is available for download at the end of this page.

For further advice on the submission of your variation please contact Ms Anne Ambrose (Tel: 020 7084 2186) or Ms Saadia Sharief (Tel: 020 7084 2951)

