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ANTIDEPRESSANTS – UPDATE ON SUICIDAL THOUGHTS AND BEHAVIOUR

IRISH MEDICINES BOARD

Further to previous IMB publications regarding the risk of suicidal behaviours associated with use of antidepressants, most recently in relation to children and adolescents, a comprehensive review of available clinical trial data for individual antidepressants was undertaken at EU and US level to further assess the risk of suicidality in adults treated with these medicines.

The review concluded that as previously suggested, young adults may be at an increased risk of suicidal behaviour when treated with antidepressants. A report summarising the data assessed was recently published and is available from www.hma.eu/222.html.

As a result of this review, it was agreed at EU level that the product information for all antidepressants should be further updated to more fully reflect the current evidence regarding the potential risk of suicidal behaviour with antidepressants and the following warning statements, some of which were already in place are now applicable for all relevant products.

Section 4.4 - Special Warnings and Special Precautions for Use

Suicide/Suicidal Thoughts or Clinical Worsening

Depression is associated with an increased risk of suicidal thoughts, self harm and suicide (suicide-related events). This risk persists until significant remission occurs. As improvement may not occur during the first few weeks or more of treatment, patients should be closely monitored until such improvement occurs. It is general clinical experience that the risk of suicide may increase in the early stages of recovery.

Other psychiatric conditions for which <name of antidepressant> is prescribed can also be associated with an increased risk of suicide-related events. In addition, these conditions may be co-morbid with major depressive disorder. The same precautions observed when treating patients with major depressive disorder should therefore be observed when treating patients with other psychiatric disorders.

Patients with a history of suicide-related events, or those exhibiting a significant degree of suicidal ideation prior to commencement of treatment are known to be at greater risk of suicidal thoughts or suicide attempts, and should receive careful monitoring during treatment. A meta-analysis of placebo-controlled clinical trials of antidepressant drugs in adult patients with psychiatric disorders showed an increased risk of suicidal behaviour with antidepressants compared to placebo in patients less than 25 years old.

Close supervision of patients and in particular those at high risk should accompany drug therapy especially in early treatment and following dose changes. Patients (and caregivers of patients) should be alerted about the need to monitor for any clinical worsening, suicidal behaviour or thoughts and unusual changes in behaviour and to seek medical advice immediately if these symptoms present.

Section 4.8 – Undesirable Effects

This section of the product information has been updated to reflect information available regarding reports of suicidal thoughts or behaviour which have been reported with the individual products and may be presented in tabular form.

Revised Wording for the Patient Information Leaflet

Thoughts of Suicide and Worsening of your Depression or Anxiety Disorder

If you are depressed and/or have anxiety disorders you can sometimes have thoughts of harming or killing yourself. These may be increased when first starting antidepressants, since these medicines all take time to work, usually about two weeks but sometimes longer.

You may be more likely to think like this:

- If you have previously had thoughts about killing or harming yourself.
- If you are a young adult. Information from clinical trials has shown an increased risk of suicidal behaviour in adults aged less than 25 years with psychiatric conditions who were treated with an antidepressant.

If you have thoughts of harming or killing yourself at any time, **contact your doctor or go to a hospital straight away.**

You may find it helpful to tell a relative or close friend that you are depressed or have an anxiety disorder, and ask them to read this leaflet. You might ask them to tell you if they think your depression or anxiety is getting worse, or if they are worried about changes in your behaviour.

Healthcare professionals are reminded to adhere to the approved recommendations for use of antidepressants and to closely monitor patients during use, advising them to report any symptoms associated with their treatment to their doctor. Suspected adverse reactions should be notified to the IMB in the usual way.