

## **QUESTIONS AND ANSWERS ON FINDINGS OF CSM EXPERT WORKING GROUP**

### **Why is there new advice for prescribers and patients?**

In 2003 an Expert Working Group of the Committee on Safety of Medicines (CSM) was set up to consider further the safety of SSRIs, with a particular focus on suicidal behaviour and withdrawal reactions. The Expert Group has examined all the evidence available from a wide range of sources and had a specific objective to listen to patient experiences.

### **What is the new advice?**

The advice being communicated to health professionals focuses on the use of SSRIs in adults and concludes that the balance of risks and benefits of all SSRIs in adults remains positive. However, prescribers and patients should be more aware of the side effect profile of these medicines and the need for monitoring of patients being treated for depressive illness or anxiety disorders. [CSM has previously advised that most SSRIs should not be used in the treatment of depressive illness in children and adolescents.](#)

No one needs to stop treatment as a result of this new advice. If after reading the details of the advice anyone is concerned, they should contact their doctor to discuss their treatment.

### **Are SSRIs associated with an increased risk of suicide?**

Depressive illness is itself associated with an increased risk of suicide. Large population studies suggest that there is no increase in the risk of suicide and suicidal behaviour in relation to SSRIs compared to other antidepressants. Clinical trial data cannot rule out a modest increase in the risk in relation to SSRIs compared with placebo. For a small number of people there may be an increase in suicidal thoughts and behaviour with any antidepressant, including SSRIs, particularly in the early stages of treatment. For these reasons, careful and frequent monitoring by healthcare professionals and other carers is important, especially in early treatment.

### **If these drugs cause suicide, why don't you just ban them?**

There is no evidence that SSRIs increase the risk of suicide to a greater extent than other antidepressants. These drugs are beneficial for the majority of patients with depressive illness and anxiety disorders. These conditions can be life-threatening and have a huge impact on the lives of those that suffer from them, and effective treatments are to be welcomed. However, no medical intervention is totally without risk – the answer is not to ban medical treatments, but to ensure that doctors and patients are aware of the risks and know how to monitor and manage them.

### **Are these drugs addictive?**

It has been known for some time that all SSRIs cause withdrawal reactions on stopping. While they do not appear to cause dependence in the way that alcohol or opiates do, a significant number of patients experience withdrawal reactions on stopping or reducing their medicine, and in some of these patients the withdrawal reactions are severe and disabling.

SSRIs should not be stopped suddenly. The dose should be reduced gradually at the end of treatment. For some people this may have to be over many weeks.

**What happens when SSRIs are stopped?**

Withdrawal symptoms can include feeling dizzy, shaky, sick, anxious, agitated or confused. Some people experience tingling sensations, pins and needles, burning sensations, electric-shock like sensations or increased sweating. Difficulty in sleeping and strange dreams can also occur.

**Why is it not safe to take this drug if you are aged 18 or under, but suddenly OK if you are 19?**

The side-effects of many of these drugs do seem to be greater in trials conducted amongst under 18s **and** most have not been shown to be beneficial in treating the illness, which means that the risks outweigh any benefits. In trials amongst over 18s, the illness is effectively treated. This is why we take age 18 as the watershed point. However people mature at different rates so it is very important that doctors, patients and their family and friends are aware of the need for care in using these drugs in young people, who are in any case at higher risk of suicidal thoughts and self harm than older age groups. That is why the CSM (and the NICE guidelines) recommended close monitoring as a precaution for young adults.

**I don't think I need to be on an SSRI – should I stop my medicine?**

No one should stop their SSRI treatment without first discussing it with their doctor. It is extremely important that no one stops treatment suddenly.

**I am currently taking an SSRI at the recommended dose but my condition has not improved/I seem to have got worse. Do I need a higher dose?**

For most SSRIs there is no evidence from clinical trials in depressive illness that increasing the dose beyond that recommended provides any additional benefit, it is however possible that some individuals may benefit from higher than recommended doses. If the recommended dose is not helping you, you should consult your doctor.

The unwanted effects that occur in some people soon after starting therapy may be difficult to distinguish from the underlying condition. There is evidence that increasing the dose in this situation may be detrimental.

**What are the “SSRIs”?**

The “SSRIs” or Selective Serotonin Reuptake Inhibitors are an important group of medicines used in the treatment of depressive illness and anxiety related disorders. There are a number of different medicines in the SSRI group and each has an individual name – Cipramil (citalopram), Ciprallex (escitalopram), Faverin (fluvoxamine), Lustral (sertraline), Prozac (fluoxetine) and Seroxat (paroxetine). Two other antidepressants with a slightly different mechanism of action, Efexor (venlafaxine) and Zispin (mirtazapine) were also included in the review.

### **What are the possible side-effects of SSRIs?**

Any medicine can cause side effects in some people. For most people these side effects are not severe and they get better over time. The most common side effects of SSRIs are nausea (feeling sick), insomnia (difficulty sleeping), drowsiness, headache or a sense of feeling tense or nervous.

### **Venlafaxine (Efexor)**

#### **What is the new advice on Efexor?**

The CSM has recommended that treatment with venlafaxine (Efexor) should only be started by specialists (including general practitioners with a special interest in mental health) and there should be arrangements in place for ongoing supervision of the patient. Importantly, new advice is that patients with heart disease should not be given Efexor.

#### **What is meant by ‘specialists’?**

Specialists include psychiatrists and medical practitioners with a special interest in mental health.

#### **What should I do if I am taking Efexor?**

Patients who are currently doing well on treatment with Efexor can continue to take their medicine as normal.

Patients with known heart disease or significant risk factors for heart disease should be reviewed at their next routine appointment with their doctor, and a decision made to complete the course of Efexor, after evaluating the balance of risks and benefits in the individual case.

#### **Why have you made special recommendations in relation to Efexor?**

There are a number of different reasons which the CSM took into account when reaching their decision. Data from the Office of National Statistics show that venlafaxine is involved in a higher rate of deaths from overdose than the SSRIs. There is evidence that Efexor may affect cardiac function. In addition, Efexor is also one of the drugs more likely to cause withdrawal reactions than some other SSRIs.

#### **If Efexor is more dangerous than the others, why use it at all?**

It is not so much that this drug is more dangerous, but rather that it poses a different set of risks which need closer monitoring. That is why CSM has advised that new patients should be started on Efexor under specialist supervision. It is an important drug in treating many patients with depressive illness and there is no reason not to use it with the right patients and with appropriate monitoring.

Currently Efexor is largely used in patients whose depressive illness has not responded to other antidepressants, and it remains as a treatment option for these patients.