Medicines and Healthcare products Regulatory Agency

Safety review of antidepressants used by children completed (reference 2003/0505)

Advisory: It is essential that patients taking SSRIs do not suddenly discontinue use of the drug. Any changes must take place under medical supervsion. Please reflect this position in reports

The majority of SSRIs (Selective Serotonin Reuptake Inhibitors) - the most commonly prescribed type of antidepressants - are not suitable to be used by under 18s, said Alasdair Breckenridge, Chair of the Medicines and Healthcare products Regulatory Agency.

The new advice follows a review by a group of medical experts set up earlier this year to look at the safety of SSRIs. The group has now studied all available evidence and has found that risks of treating depressive illness in under 18s with certain SSRIs outweigh the benefits of treatment.

There is no, or insufficient, evidence from clinical trials that benefits outweigh the risks of side effects for sertraline (Lustral), citalopram (Cipramil), escitalopram (Cipralex) and fluvoxamine (Faverin). Fluoxetine, or Prozac, appears to have a positive balance of risks and benefits in the treatment of depressive illness in the under 18s.

An estimated 30 - 40,000 thousand children and teenagers are prescribed SSRIs across the UK, about half of those were treated with fluoxetine (Prozac). In June, a warning was issued about the use of paroxetine (Seroxat) in children under the age of 18, and further advice was given in September about the use of venlafaxine (Efexor). Today's advice completes the picture on the remaining five SSRIs.

Professor Gordon Duff, Chairman of the Committee on Safety of Medicines, said:

"The CSM Expert Group has delivered comprehensive advice on the use of these drugs in children and young people following a thorough review of all the evidence available. This gives parents, young people and those who treat these devastating illnesses the information they need to make informed decisions about treatment."

"Like Seroxat and Efexor, none of these drugs has ever been licensed for use in those under 18.

"We know, however, they are used in this age group outside of their licensed indications where prescribers make a judgement on their own responsibility that it is the correct treatment for a particular patient.

"It is therefore important that patients, parents and doctors are aware of the new advice. Young people with depressive illness currently taking any SSRI other than fluoxetine should not stop taking their medicine but should consult their doctor for advice on treatment".

In a new step, data from the clinical trials on SSRIs and children, supplied by the drug companies to the Expert Group, is also being released today to allow clinicians to assess the information on which the new advice is based.

The Expert Group is now focusing on the ongoing review of the efficacy and safety of SSRIs in adults, and this should be completed in the first half of next year.

Professor Ian Weller, Chairman of the Working Group, said:

"We are now working on completing the review of the safety of these medicines in adults. This is one of the most comprehensive reviews of a class of medicines ever to be undertaken and it is painstaking work, examining evidence from literally hundreds of clinical trials but we are determined to see this important work through. It should be complete in the Spring. In the meantime, there is no evidence to suggest that the risks of treatment outweigh the benefits in adults. Patients who are experiencing any side effects or are concerned about their treatment should discuss these with their doctor".

Notes to editors

1. The SSRIs for which the CSM Expert Group have judged the balance of risks and benefits to be negative or on which there is too little evidence to make a decision are sertraline (trade name Lustral), citalopram (trade name Cipramil), escitalopram (trad name Cipralex), fluvoxamine (trade name Faverin), paroxetine (trade name Seroxat) and venlafaxine (trade name Efexor).

2. The CSM is an independent Committee of scientific experts that advise Government on the safety, quality and effectiveness of medicines, including vaccines. It is also responsible for promoting the collection and investigation of reports on suspected adverse reactions to medicines already on the market. The MHRA is the executive arm of the UK's Drug Licensing Authority and is responsible for all aspects of the regulation of medicines in the UK.

3. In April 2003, the CSM established an Expert Working Group to consider the safety of Selective Serotonin Reuptake Inhibitors (SSRIs), used for the treatment of depressive illness and anxiety disorders since the late 1980s. The Group incorporates specialist experts in the clinical management of depressive illness in childhood and adolescence.

4. Regulatory action to amend the marketing authorisations for all the products has been initiated by the MHRA and will be carried through as a matter of urgency.

5. Prescribing advice and clinical trials data is available on www.mhra.gov.uk

For further information on this part of our site, please contact our Media Centre, Department of Health, Richmond House, 79 Whitehall, London SW1A 2NL. Telephone 020-7210 5226 (weekdays 0930 - 01730), 07050-073581 (other times), fax 020-7210 5434.

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Fonte: http://www.antidepressantsfacts.com/2003-10-12-05-05-MHRA-CSM-SSRIs.htm