

From the Chief Medical Officer:



Department of
**Health, Social Services
and Public Safety**

URGENT COMMUNICATION

HSS(MD)13-2006

An Roinn

**Sláinte, Seirbhísí Sóisialta
agus Sábháilteachta Poiblí**

www.dhsspsni.gov.uk

To: All General Practitioners (for cascade to practice nurses and non-principals working in your practice)
Community Pharmacists
Medical Directors of HSS Trusts for cascade to:
- Consultant Psychiatrists
- Consultant Clinical Psychologists
Directors of Public Health in HSS Boards
Directors of Pharmaceutical Services in HSS Boards (for cascade to prescribing advisers)
Directors of Pharmaceutical Services in HSS Trusts
Directors of Nursing in HSS Boards
Directors of Nursing in HSS Trusts (for cascade to Community Psychiatric Nurses)
Directors of Primary Care – for cascade to Out-of-Hours Services
GP Advisers in HSS Boards
Chief Executive, RQIA, for cascade to Regulated Services
Regional Medicines Information Service

Castle Buildings
Upper Newtownards Road
STORMONT, BT4 3SQ
Tel: 02890520563
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Email:
elizabeth.mitchell@dhsspsni.gov.uk

Your Ref:
Our Ref:
Date: 8 May 2006

Dear Colleague

PAROXETINE (SEROXAT) ? RISK OF SUICIDAL BEHAVIOUR IN ADULTS

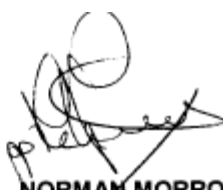
The attached information on Paroxetine (Seroxat) ? Risk of Suicidal Behaviour in Adults issued by Professor Gordon Duff, Chairman, Commission on Human Medicines, further highlights the importance of monitoring all patients treated with SSRIs for worsening of their symptoms or mood changes.

Please ensure that this information is cascaded to relevant health and social care professionals.

Yours sincerely


PP. ELIZABETH MITCHELL (DR)
(ACTING) CHIEF MEDICAL OFFICER


MARTIN BRADLEY (MR)
CHIEF NURSING OFFICER


NORMAN MORROW (DR)
CHIEF PHARMACEUTICAL OFFICER

cc: Director of Healthcare – PMS

This letter is available at www.dhsspsni.gov.uk and also on the DHSSPS Extranet which can be accessed directly at <http://extranet.dhsspsni.gov.uk> or by going through the HPSS Web at <http://www.n-i.nhs.uk> and clicking on DHSSPS.

FROM THE CHAIRMAN, COMMITTEE ON SAFETY OF MEDICINES

Dear Colleague,

Paroxetine (Seroxat) ? risk of suicidal behaviour in adults

I am writing to inform you about the new analyses of paroxetine clinical trials that are being published by the manufacturer of Seroxat, GlaxoSmithKline.

These new analyses examine the risk of suicidal behaviour in clinical trials in the adult population, and were conducted as part of a review by the US FDA. The new analyses highlight the importance of monitoring all patients treated with SSRIs for worsening of their symptoms or mood changes but do not alter the prescribing advice for SSRIs issued in December 2004 following the review by the CSM Expert Working Group on the Safety of SSRIs.

The new analyses are being evaluated by the Commission on Human Medicines (CHM) and the Medicines and Healthcare products Regulatory Agency (MHRA). Following our further investigations and discussions with other European regulatory agencies the Seroxat product information for prescribers and patients will be updated as needed. In the meantime, this letter reminds you of the previous advice that has been issued.

Reminder of current advice to prescribers:

Careful and frequent patient monitoring by healthcare professionals and, where appropriate, other carers, is important in the early stages of treatment with paroxetine, especially if a patient experiences worsening of symptoms or if new symptoms arise after starting treatment.

Young adults (18-29 years of age) are at a higher background risk of suicidal behaviour than older adults and therefore should be monitored particularly closely.

The key findings and recommendations of the CSM Expert Working Group on the Safety of SSRIs in relation to the risk of suicidal behaviour in adults can be found at Annex 1. The Group's full report can be found on the MHRA website (<http://www.mhra.gov.uk>).

Further information on the use of SSRIs, including paroxetine, in the treatment of depression and anxiety can be found in the NICE guideline on the management of depression in primary and secondary care (<http://www.nice.org.uk>).

Please report any suspected adverse reactions to paroxetine via the Yellow Card Reporting Scheme to the CHM/MHRA (<http://www.yellowcard.gov.uk>)

For further information please call the Medicines and Healthcare products Regulatory Agency on 02070842000 or visit the website (<http://www.mhra.gov.uk>)

Yours sincerely

Professor Gordon Duff
Chairman, Commission on Human Medicines

Annex 1

Key findings of CSM's Expert Working Group on the Safety of SSRIs

Use of SSRIs in adults ? suicidal behaviour

The conclusions of the Group on this issue can be summarised as follows:

There is epidemiological evidence that the risk of self-harm in depressed patients is greatest around the time of presentation to medical services. It is general clinical experience that the risk of suicide may increase in the early stages of treatment for depressive illness.

Careful and frequent patient monitoring by healthcare professionals and, where appropriate, other carers, is important in the early stages of treatment, particularly if a patient experiences worsening of symptoms or new symptoms after starting treatment.

Studies indicate that increases in the prescribing of SSRIs have not been associated with an increase in population suicide rates, although interpretation of these findings is difficult as a range of factors influence population trends in suicide.

From the available clinical trial data, both published and unpublished, a modest increase in the risk of suicidal thoughts and self-harm for SSRIs compared with placebo cannot be ruled out. There is insufficient evidence from clinical trial data to conclude that there is any marked difference between members of the class of SSRIs, or between SSRIs and other antidepressants, with respect to their influence on suicidal behaviour.

Evidence from non-experimental studies based on the General Practice Research Database indicates that there is no increased risk of suicidal behaviour with SSRIs compared with tricyclic antidepressants (TCAs).

There is no clear evidence that there is an increased risk of self-harm or suicidal thoughts when SSRIs are discontinued.

Evidence of a relationship between suicidal behaviour and increasing/decreasing dose is not robust; however, patients should be monitored around the time of dose changes for any new symptoms or worsening of disease.

Young adults

The increased risk of suicidal behaviour seen in children and adolescents with depressive illness treated with SSRIs raised the question as to whether there was a similar increased risk in young adults. The clinical trial data for each product was reviewed in relation to a possible effect in young adults, and the GPRD study looked specifically at this age group. From these analyses, the Group concluded that there is no clear evidence of an increased risk of self-harm and suicidal thoughts in young adults of 18 years or over. However, given that individuals mature at different rates and that young adults are at a higher background risk of suicidal behaviour than older adults, as a precautionary measure young adults treated with SSRIs should be closely monitored. The Group also recommended that in further research on the safety and efficacy of SSRIs, young adults should be assessed separately.