



**GlaxoSmithKline**  
Pharmaceuticals

October 9<sup>th</sup>, 2002

**GlaxoSmithKline**  
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Dear Healthcare Professional,

As you may already know, BBC's investigative journalism show 'Panorama' has been preparing a programme on Seroxat which will air this Sunday, 13<sup>th</sup> October.

While we do not know the full content of the programme, we anticipate that there will be interviews with individuals who have taken Seroxat around topics such as withdrawal/ discontinuation symptoms (symptoms already well described in the Seroxat prescribing information). The programme may also contain unfounded allegations of dependency/addiction or self-harm and suicide.

These topics are clearly highly disturbing to patients who take our product in good faith, and the programme could quite understandably lead to a number of concerned patients contacting you.

We at GlaxoSmithKline want to reiterate that we stand firmly behind Seroxat. We believe in its effectiveness and its well-established safety profile, which is based on a wealth of robust clinical data involving thousands of physicians and over 1.3 million patient treatments worldwide since its launch in 1991.

If you have any medical queries or if we can provide further support to you, please do not hesitate to contact our medical information INFORM line on 1 800 244 255.

Yours faithfully,

**Martina Dempsey**  
Director of Medical and Regulatory Affairs

**GlaxoSmithKline (Ireland) Ltd.**  
(Formerly Glaxo Wellcome Ltd.)

Registered in Ireland No. 15513  
Registered office: Stonemason's Way, Rathfarnham,  
Dublin 16, Ireland.

Directors: **D.M. Hurt (Br.)**, **D.Y. Schleiter (Fr.)**  
**S.A. Ross (USA)**



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October 17, 2002

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**Seroxat 20mg tablets, 30mg tablets, oral liquid (PA 49/50/1-0)**

Dear Doctor,

GlaxoSmithKline would like to advise you that packs of the above Seroxat presentations, which have been supplied to patients from pharmacies, contained a Patient Information Leaflet (PIL) that is not the most up to date version. Stocks being supplied from wholesalers to pharmacies in the coming days will contain the most recently approved PIL.

The difference in the old and new PIL relates to class labelling, approved by the Irish Medicines Board for inclusion in packs of all members of the Selective Serotonin Reuptake Inhibitors (SSRIs) drug class which reminds depressed patients of the inherent risk of suicide associated with their condition. The specific wording for Seroxat is:

'Occasionally, the symptoms of depression may include thoughts of harming yourself or committing suicide. Until the full antidepressant effect of your medicine becomes apparent, it is possible that these symptoms may increase in the first few weeks of treatment. Tell your doctor immediately or go to the nearest hospital if you have any distressing thoughts or experiences during this initial period or at any other time.'

I wish to emphasise that there are no issues or concerns regarding the safety, efficacy or quality of Seroxat.

Please find enclosed a copy of the most up to date PILs for your information.

We apologise for any inconvenience caused.

Yours sincerely,

Martina Damspey  
Director Medical & Regulatory Affairs

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