



Stewart Hosie

Member of Parliament for
Dundee East

HOUSE OF COMMONS

LONDON SW1A 0AA

Wednesday, 15 November 2006

Mr Derek Scott
51 Linfield Street
Happyhillock
Dundee
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Dear Derek

Thank you for your letter of 23 October 2006. Please also find enclosed the correspondence which I have received from the Clerk of Public Petitions in relation to your petition.

I will raise the issue of the apparent failure of MHRA to carry out a review of *"all of the available Paroxetine (Seroxat) data"*.

Regarding our concerns regarding MHRA, and in particular the recommendation that they should not be as close to the pharmaceutical industry, I will ask the government to explain why they continue to allow the MHRA to be funded by the Industry rather than general taxation.

I will be in further contact with you in due course.

Yours sincerely

Stewart Hosie MP
SH/THoP

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27.10.06

Please find enclosed a copy of the departmental observations on the petition presented by you on the date shown on the attached sheet.

CLERK OF PUBLIC PETITIONS

SUPPLEMENT TO THE VOTES AND PROCEEDINGS

Observations by the Secretary of State for Health on the Petition [21st June] from Mr D Scott and others for a moratorium on the prescription of Seroxat.

The Government takes the concerns expressed about the side effects of Seroxat very seriously. The safety of Seroxat has been under consideration by the Medicines and Healthcare products Regulatory Agency (MHRA) and other regulatory authorities within the European Union and worldwide for a number of years.

The report of a rigorous 18 month long investigation by an Expert Working Group of the Committee on Safety of Medicines into suicidal behaviour and withdrawal reactions associated with Seroxat (paroxetine) and other antidepressants of the same class (the Selective Serotonin Reuptake Inhibitors, SSRIs) was published in December 2004, alongside the publication of guidelines on the treatment of depression by the National Institute of Clinical Excellence.

In reaching its conclusions the Expert Working Group considered a large body of safety evidence from a wide range of sources including clinical trials, reports of patients' experiences and feedback from meetings with patient support groups including the Seroxat Users Group.

The Expert Working Group concluded that the balance of risks and benefits of most SSRIs for the treatment of depression in children and adolescents was negative and they should not be used in this population. The Expert Working Group concluded 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 close monitoring of patients.

Healthcare professionals were informed of the key findings of the Group, and both the final report of the Group and the letter to health professionals were made available on the MHRA website. A questions and answers document for patients was also published on the website, a statement was laid in Parliament, and a press conference was held to inform the national press of the findings of the Group.

At the same time as the Expert Working Group's review, a detailed review of the balance of risks and benefits of Seroxat was conducted by the European Commission's scientific advisory committee, the Committee on Medicinal Products for Human Use (CHMP). The Netherlands took the lead in the review and the conclusions were consistent with those of the CSM's Expert Working Group.

The safety of Seroxat remains under continual review and earlier this year GlaxoSmithKline, which manufactures Seroxat, published an updated analysis of their adult clinical trial database. These data are under consideration by the MHRA, other European Regulatory Authorities, and the Food and Drug Administration in the United States of America and new prescribing advice will be issued as appropriate.

We want to ensure that patients and prescribers make fully informed prescribing decisions and the Seroxat patient information leaflet has been extensively user-tested to ensure that the information on the use of Seroxat and possible side effects is clear and accessible.

The Health Select Committee is appointed by the House of Commons to examine the expenditure, administration and policy of the Department of Health and its associated bodies. Its remit does not include investigation of the safety of individual medicinal products. Such investigations are the remit of the Government's independent scientific advisory committee, the Commission on Human Medicines (formerly the Committee on Safety of Medicines).

20th October 2006

SUPPLEMENT TO THE VOTES AND PROCEEDINGS

PETITION FROM MR D SCOTT AND OTHERS

21st June 2006

To the House of Commons.

The Petition of Mr D Scott and others,

Declares that there is deep concern about the side effects that many people believe that they have suffered from being prescribed the drug Seroxat.

Further declares that the Health Select Committee should carry out an investigation into the drug and its possible side effects.

The Petitioners therefore request that the House of Commons urge Her Majesty's Government to place a moratorium on the prescription of Seroxat to new patients until a review has been carried out on the large body of evidence which now exists concerning the side effects of this drug.

And the Petitioners remain, etc.