



Stewart Hosie

Member of Parliament for
Dundee East

HOUSE OF COMMONS

LONDON SW1A 0AA

Wednesday, 20 September 2006

Mr Derek Scott
51 Linfield Street
Happyhillock
Dundee
DD4 8LJ

Dear Derek

Correspondence from Department of Health

I write to you with the above enclosure.

As you will have gathered from your email correspondence with Craig I am very angry about the complacent way the Health Minister continues to appear on this matter.

I am equally concerned that, while the government agreed that the regulatory system requires to be more transparent, the government are now engaged in "*devising appropriate terms of reference and preparing a timetable for the review in the autumn*".

There appears to be little urgency on both matters.

We appear to be no further forward and I will now be investigating the possibility of a Whitehall debate in the Commons after the recess ends.

On an unrelated topic, please find enclosed a copy of the letter which I have written to Telewest regarding the issue you raised. I will be in further contact with you in relation to this once I receive the reply.

As always, please feel free to contact the office if you have any further queries.

Yours sincerely

Stewart Hosie MP

**Please address all
correspondence to**

SNP Parliamentary Office
8 Old Glamis Road
Dundee
DD3 8HP

Tel. 01382 623200
Fax. 01382 903205

e-mail:
stewart@stewarthosie.com

Also at:

House of Commons
London, SW1A 0AA

Tel. 0207 219 8164

e-mail:
hosies@parliament.uk

www.stewarthosie.com

From the Minister of State
Andy Burnham MP



PO00000132087

Stewart Hosie MP
SNP Parliamentary Office
8 Old Glamis Road
Dundee
DD3 8HP

Richmond House
79 Whitehall
London
SW1A 2NS
Tel: 020 7210 3000

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Dear Stewart,

Thank you for your letter of 9 August to Patricia Hewitt about Seroxat.

I am advised by the Medicines and Healthcare products Regulatory Agency (MHRA) that, based on a comprehensive review of the available data, the balance of risks and benefits of all selective serotonin re-uptake inhibitors (SSRIs), including Seroxat, is considered to be positive in their licensed indications. With this in mind, there are currently no plans to suspend their use in adults. When reaching a decision about the most appropriate treatment it is important that prescribers and patients are fully aware of the potential side effects of these medicines and the need for close monitoring of patients who are being treated for depressive illness or anxiety disorders.

However, I can assure you that the safety of Seroxat remains under close constant scrutiny by the MHRA and healthcare professionals, and patients have been provided with information on its safe use as and when new data have arisen.

For example, the MHRA took action ahead of other regulators to issue clear advice in 2003 that Seroxat, together with a number of other SSRIs, should not be used in the treatment of children and adolescents with depressive illness. It continued to issue advice on the use of SSRIs throughout the course of the Review by the Committee on Safety of Medicines Expert Working Group on the Safety of SSRIs, prior to the publication of its report in December 2004.

More recently, the MHRA issued advice in December 2005 about the safety of use during pregnancy. It also issued further advice in May 2006 following a new analysis of the risk of suicidal behaviour in the adult population. These data are currently under consideration by the MHRA, other European Regulatory Authorities, and the Food and Drug Administration in the United States of America. When this work has been completed new prescribing advice will be issued as appropriate.

Turning to the role and status of the MHRA, Recommendation 20 (paragraph 36) of the *Report of the Health Select Committee into the Influence of the Pharmaceutical Industry* (published in April 2005), concerned the need for an independent review of the MHRA. It proposed a framework within which that review should be conducted and did refer to the need for greater independence from government and from the industry.

In its response, published in September 2005, the Government agreed with the Committee that it is important for the regulatory system, and indeed the regulator, to operate in as transparent a way as possible. It pointed out the range of independent reports that have been conducted in recent years, including the National Audit Office's Value for Money study into the MCA, Dr Jeremy Metter's Independent Review of Access to the Yellow Card Scheme, the Report of the Committee on the Safety of Medicines Expert Working Group on SSRIs, mentioned above, and a major review of the Agency's communications. The issues identified are currently being addressed by the Agency as part of a development programme which is bringing changing attitudes, practices and processes to the Agency.

The Government accepted the need for a review of the operations of the MHRA which would examine whether the Agency is meeting the needs of patients and the expectations of society. The terms of reference, the methodology and timing of such a review need further consideration.

However, as stated by the Government in its response, the review should be informed by expert knowledge of the relevant scientific and social issues, international benchmarking against other Agencies, and an understanding of the principles underpinning medicines (and devices) regulation.

Officials will be devising appropriate terms of reference and preparing a timetable for the review in the autumn.

I hope this reply is helpful.

Best wishes,
Andy.

ANDY BURNHAM