Health and Ageing Sub (145)

COMMONWEALTH OF AUSTRALIA

Ageing and Aged Care
GPO Box 9848, Canberra ACT 2601
Telephone: (02) 6289 5480 Fax: (02) 6289 1330
ABN 83 605 426 759

Commonwealth Department of
Health and
Ageing

Ms Bev Forbes
Committee Secretary
Standing Committee on Ageing
House of Representatives
Parliament House
CANBERRA ACT 2600

Dear Ms Forbes

**HOUSE OF REPRESENTATIVES STANDING COMMITTEE ON AGEING - QUESTION ON NOTICE**

I would like to thank the House of Representatives Standing Committee on Ageing for the opportunity for staff from the Department of Health and Ageing to appear before a public hearing on 7 February 2003.

At the hearing, Dr Ruth Lopert, Assistant Secretary, Pharmaceutical Benefits Branch, took a Question on Notice from Mr Hartsuyker regarding clinical trials of Alzheimer's drugs. The Question and the Department's response are at Attachment A.

If you would like to discuss the matter, please contact Mr Kevin Vassarotti on (02) 6289 5212.

Yours sincerely

Nick Mersiades
First Assistant Secretary
Ageing and Aged Care Division
02 May 2003

ATTACHMENT A

Dr Lopert,

The extract below has been taken from the Draft Hansard of this Department's appearance before the House of Representatives Standing Committee on Ageing. It provides details of the QoN you took regarding clinical trials of Alzheimer's drugs.

"Mr HARTSUYKER Mr Bruen, you mentioned that to date there has been little success in improving the situation with regard to Alzheimer's. I understand there is quite a range of clinical trials going on at the moment. Are those trials showing positive results at this point in time?

Mr BRUEN My colleague here reminded me that two drugs have recently come onto the market.

Dr LOPERT I would like to take up Mr Bruen's point. There are currently three medications for the treatment of mild to moderate Alzheimer's disease funded on the Pharmaceutical Benefits Scheme. I am not aware of any particular clinical trials that have been brought to our attention or other drugs currently under consideration. I would have to take that question on notice."

I hope this assists you in preparing a response.

Penny Dakin
Office for an Ageing Australia
6289 8453

**Answer (TGA input included):**

In Australia the conduct of clinical trials using unapproved medical products is regulated by the Therapeutic Goods Administration (TGA). These trials may be conducted under either the Clinical Trial Notification (CTN) Scheme or Clinical Trial Exemption (CTX) Scheme. Sponsor companies are, however, not required to provide reports to the TGA on the efficacy outcomes of clinical trials.

Detailed evaluations of clinical trial results in any given therapeutic area are not usually undertaken until such time as a sponsor submits an application for marketing approval to the TGA or a submission for listing on the Pharmaceutical Benefits Scheme. In each case the content of the applications is considered commercial-in-confidence.

Information about recently conducted trials or trials in progress would be available in the medical literature.