



AUSTRALIAN SENATE

COMMUNITY AFFAIRS

LEGISLATION COMMITTEE

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Therapeutic Goods Amendment Bill 2005

On 7 September 2005 the Senate, on the recommendation of the Selection of Bills Committee, has referred the provisions of the above Bill to the Committee for inquiry and report by 28 October 2005. [On 13 October 2005 the Senate extended the reporting date to 7 November 2005]

The Bill, Explanatory Memorandum, second reading speech and the Parliamentary Library's Bills Digest may be accessed on the Internet at <http://www.aph.gov.au/ParlInfo/BillsNet/main.htm>

In recommending the reference of the Bill to the Committee, the Selection of Bills Committee provided the following issues for consideration.

To examine the provisions of the Bill relating to new enforcement options for the TGA to:

- a) identify if the Bill provides sufficient detail on the scope of alleged breaches to which infringement notices may apply, on the use of alternatives to court proceedings, and the extent to which the processes of investigation of offences will be in line with procedural fairness (including the use of media during investigations and prosecutions);
- b) ascertain if the Bill adequately accommodates differences between registrable and listable goods;
- c) examine inequity implications for Australian based manufacturers due to the non-applicability of the civil penalty regime to foreign entities; and
- d) examine the need for ad hoc appeals mechanism against the imposition of an infringement notice and a fine under the civil penalties regime currently included in the Guidelines, to be included in the Regulations to preserve the appeal mechanism and prevent arbitrary variations and application.

The Committee invites written submissions on the Bill which should be lodged with the Committee by Wednesday, 5 October 2005. The Committee prefers to receive submissions electronically as an attached document - email: community.affairs.sen@aph.gov.au – otherwise by fax (number 02 6277 5829).

The Committee intends to hold a public hearing on the Bill on Thursday, 13 October 2005.