

2<sup>nd</sup> November 2005

Mr Elton Humphery  
Committee Secretary to the Australian Senate Community  
Affairs Legislation Committee  
Parliament House  
CANBERRA ACT 2600

Dear Mr Humphery

**Re: Therapeutic Goods Amendment Bill 2005**

Blackmores Ltd wishes to make a brief submission to the Community Affairs Legislation Committee regarding the Therapeutic Goods Amendment Bill 2005. The Bill is intended to introduce means for punishing offending behaviour with civil penalties, infringement notices and enforceable undertakings, in addition to criminal prosecutions.

**“Trial by media” concerns**

Industry has previously expressed concern that provision within the Bill for the issuing of media releases allows for the potential for ‘trial by media’ situations that have very serious implications for industry and could affect the outcomes of any legal recourse. Whilst it is not the preferred option, we have some verbal assurance from the Parliamentary Secretary that this will be addressed in the guidelines that will accompany the Bill.

**Development of guidelines to accompany Bill**

It is most important that the guidelines be developed prior to the introduction of the Bill; a committee comprising representation from industry and government should be established to develop the guidelines in a consultative, co-regulatory manner – the current Office of Complementary Medicine/industry group that has developed Australian regulatory guidelines for complementary medicines is a good model for this committee.

**Bill doesn’t accommodate differences between listed and registered goods**

Blackmores is not opposed to the concept of infringement notices from a regulator, however we believe that the level of fines suggested in the Bill is excessive and has no relationship to the level of public risk involved – whilst the level of fines may be relevant to over-the-counter and prescription drugs, it is not relevant to low-risk, listable complementary medicines.

Finally, with regard to the future of the Bill’s impact under the provisions of the new trans-Tasman agency, we understand that the New Zealand government is strongly opposed to incorporating these amendments in future harmonisation arrangements so, at best, the impact of the amendments will be temporary and, on the downside, has the potential to derail the trans-Tasman arrangements.

Yours faithfully



**Philip Daffy**  
**Director – Research & Development/Corporate Affairs**  
**Blackmores Ltd**